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IN THE UNITED STATES DISTRICT COURT  
DISTRICT OF UTAH CENTRAL DIVISION

BRIGHAM YOUNG UNIVERSITY, a Utah  
Non-Profit Education Institution; and Dr.  
DANIEL L. SIMMONS, an individual,

Plaintiffs,

vs.

PFIZER, INC., a Delaware corporation; G.D.  
SEARLE & COMPANY, a Delaware  
corporation; G.D. SEARLE LLC, a Delaware  
limited liability company; MONSANTO  
COMPANY, a Delaware corporation; and  
PHARMACIA CORPORATION, a Delaware  
corporation,

Defendants.

Case Number: 2:06CV-890-BTS (BCW)

**RESPONSE IN OPPOSITION TO  
DEFENDANTS' MOTION FOR PARTIAL  
SUMMARY JUDGMENT ON  
PLAINTIFFS' CLAIM THAT  
DEFENDANTS HAVE  
MISAPPROPRIATED "PROJECT" AND  
"COMPILATION" TRADE SECRETS**

**(RESPONSE TO DEFENDANTS'  
MOTION NO. 6)**

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## INTRODUCTION

It is well-established, and Pfizer admits, that a “compilation of information” may constitute a trade secret, even when the compilation is only a “combination of generally known elements or steps” that are combined in a unique way—a combination Utah’s Supreme Court has referred to as a “vision.”<sup>1</sup> And determining whether such a compilation constitutes a trade secret “is an intensely factual inquiry,” that requires a “trade secret analysis of the ‘vision’ as a whole.”<sup>2</sup> If a jury finds that a particular combination of information and materials that a plaintiff provided a defendant was a “unique combination” of elements that “represent[ed] a valuable contribution attributable to the independent efforts” of the plaintiff, then it can qualify as a valid trade secret.<sup>3</sup>

BYU has provided a detailed trade secret disclosure listing seventy trade secrets, and has also asserted that some or all of those individual trade secrets collectively constitute “compilation” trade secrets. BYU provided detailed descriptions of such in response to Pfizer Interrogatory No. Eight,<sup>4</sup> in the Supplemental Expert Report of BYU expert Mr. Fellmeth,<sup>5</sup> and in the list prepared by Mr. Ricker, BYU’s 30(b)(6) witness on trade secrets.<sup>6</sup>

In its present motion, Pfizer doesn’t challenge any of these individual trade secrets, saying it will address those “elsewhere or at trial.” Pfizer Mem. at ii. Rather, Pfizer simply seeks summary judgment on what it calls BYU’s “project” and “compilation” trade secret claims, arguing that these “are not identified with the specificity required to warrant protection” under

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<sup>1</sup> *USA Power, LLC v. PacifiCorp*, 235 P.2d 749, ¶¶ 43, 45 (Utah 2010) (reversing summary judgment when the trial court found that plaintiffs’ “vision” did not constitute a trade secret).

<sup>2</sup> *Id.*, at ¶ 45, 46.

<sup>3</sup> *USA Power*, 235 P.2d at 759, ¶ 43.

<sup>4</sup> Pls. Amd. 2<sup>nd</sup> Supp. Resp. to Defs. Interr. No. 8, 10 Dec 08, Ex. 57.

<sup>5</sup> Supp. Expert Report of A. Fellmeth, 10 Jun 11, at 2-4, Ex. 26.

the Uniform Trade Secrets Act (the “UTSA”). Pfizer Mem. at ii.<sup>7</sup> Logically, though, since Pfizer doesn’t contest the particularity of the individual trade secrets, its challenge to a combination of trade secrets comprised of some of the individual secrets necessarily falls flat.

BYU has identified with great particularity the core set or body of information and biological materials it provided Monsanto. Indeed, none of the cases on which Pfizer relies involved—as this case does—a long list of individual trade secrets that the moving party did not contest. Thus Pfizer’s “insufficient particularity” cases are easily distinguishable.

Moreover, while BYU does claim a compilation trade secret it refers to as the “project,” and also claims that some unique combinations of its individual trade secrets may have independent economic value, BYU does not claim just a single, “compilation trade secret.” Thus, to the extent Pfizer’s motion contends that BYU’s “compilation trade secret” has not been identified with specificity, that’s because BYU doesn’t allege such a trade secret, at least not as Pfizer tries to define it.

The basic outline of BYU’s “project” trade secret—and its importance—can be succinctly summarized:

At a time when the pharmaceutical industry generally believed there was only a single COX gene, and that it was not possible to make a drug that would only inhibit the inducible aspects of COX, Dr. Simmons discovered definitive evidence that there were really at least two COX genes, he developed a vision and plan to “rationally design drugs that selectively inhibit

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<sup>6</sup> K. Ricker, “Substance and Identity of BYU’s Trade Secrets,” marked as Ex. 1073 to Mr. Ricker’s 2 Jun 11 deposition, Ex. 190.

<sup>7</sup> Although Pfizer calls this a motion for summary judgment on Count VIII of BYU’s First Amended Complaint (the “FAC”), Count VIII deals with the misappropriation of *all* of BYU’s trade secrets, not just the “project” and “compilation” claims. Since Pfizer explicitly states it “will address elsewhere or at trial the numerous individual alleged trade secrets,” Count VIII of the FAC will remain, regardless of the outcome of this motion.

one or the other and thus reduce unwanted side effects,” and he developed a body of scientific data and biological tools to carry out that plan, a body that no one else in the world had at that time. Those tools included biological reagents, such as COX-1 and COX-2 cDNAs and antibodies, as well as a system for using these tools to test, or “assay,” compounds for their COX-2 selectivity. By following this plan and using Dr. Simmons’s collective body of information and reagents, Monsanto in early 1992 became the first pharmaceutical company in the world to develop assays that could successfully test for COX-2 selectivity. Merck—the next pharmaceutical company to develop such assays, and therefore Monsanto’s closest competitor—did not have access to BYU’s trade secrets and therefore its management did not understand the importance and did not even begin its COX-2 program until June of 1992. By that time, Monsanto had an unbeatable head start, and Monsanto won the race to market a COX-2 selective drug.

As Pfizer’s own expert, Dr. Joseph Mancini agreed, “before senior management of a company is going to devote resources to a project, **they need to have a body of information** that’s sufficiently **convincing** to them that they should shift those resources to that project,” and is just that “body of information” that Dr. Simmons provided Monsanto, and that body of information constitutes a trade secret.<sup>8</sup>

However, contrary to Pfizer’s unsupported suggestions, neither the UTSA nor the case law interpreting it bar a jury from finding a compilation trade secret that differs from the compilation argued by the plaintiffs. Here, for example, regardless of the breadth of BYU’s claimed “project” trade secret, a jury could find that some narrower, unique, combination of individual elements qualified as a trade secret. On the facts here, for example, a jury could easily

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<sup>8</sup> J. Mancini Dep., 7 Nov 11, 108:24-109:11, Ex. 32.

find that Dr. Simmons's pair of mouse COX-1 and COX-2 clones—which Monsanto witness Dr. Seibert has admitted was the only such pair in the world—by itself constituted a valid compilation trade secret. And whether a compilation trade secret exists, and its scope and form, are quintessential issues of fact for a jury to determine.



## **BYU'S RESPONSE TO DEFENDANTS' STATEMENT OF FACTS**

### **Pfizer's Statement of Facts:**

#### **A. The Research Agreement License.**

1. BYU and Monsanto entered into a Research Agreement. [A true and correct copy of the Research Agreement is attached as Exhibit 1 to the Declaration of Philipp J. Russell filed in Support of Defendants' Motion for Partial Summary Judgment ("Russell Decl."), filed concurrently herewith.] The Research Agreement states that it is "effective as of August 1, 1991." [*Id.* at 1.]

#### **BYU RESPONSE:**

BYU admits this fact.

2. Paragraph 3.2 of the Research Agreement provides:

UNIVERSITY agrees to grant and hereby grants to MONSANTO an irrevocable, worldwide, paid-up nonexclusive license, to make, have made, use and sell all unpatented inventions developed in the PROJECT.

[*Id.* at ¶ 3.2.]

#### **BYU RESPONSE:**

BYU admits this fact.

3. In a letter to Dr. Philip Needleman of Monsanto dated March 27, 1992, Carol R. Hardman of BYU indicated that BYU was in agreement with Monsanto's desire to terminate the Research Agreement. [*See* Mar. 27, 1992 Letter from BYU (Carol Hardman) to Monsanto (Dr. Needleman); Resp. to Defs.' First Set of Reqs. for Admis. to Pl. Brigham Young Univ. at 7.]

#### **BYU RESPONSE:**

BYU admits this fact.

4. In a letter to Dr. Needleman dated May 21, 1992, Ms. Hardman communicated BYU's assumption that the Research Agreement was terminated as of March 27, 1992. [See May 21, 1992 Letter from BYU (Carol Hardman) to Monsanto (Dr. Needleman).]

**BYU RESPONSE:**

BYU admits this fact, but notes that Dr. Needleman never replied to confirm that assumption.

5. Dr. Simmons sent a letter to Dr. Needleman on May 20, 1992. [May 20, 1992 Letter from BYU (Dr. Simmons) to Monsanto (Dr. Needleman).] Attached to the letter was a document titled "Post-termination Report to Monsanto." [*Id.* at BYU-20-1614.] The Post-Termination Report states that it "describes the research done by the laboratory of Daniel L. Simmons during the period 8/1/91-3/23/91," and "is submitted within 80 days of notification of termination." [*Id.*]

**BYU RESPONSE:**

BYU admits this fact.

**B. The Alleged "Project" and "Compilation" Trade Secrets**

**1. The "Project"**

6. In his Supplemental Expert Report, Mr. Fellmeth provided a list of 70 items and opined that "plaintiffs transmitted the following information to Monsanto in the course of their collaboration" and "[c]ollectively this information constitutes a trade secret." [Fellmeth Supplemental Report at ¶ 2.]

**BYU RESPONSE:**

BYU admits that Mr. Fellmeth's report contains the quoted language.

7. Item 1 on Mr. Fellmeth's list of 70 alleged trade secrets is:

A research project and plan for the selection, testing, and modifying of nonsteroidal anti-inflammatory drugs for COX-2 selectivity by establishing the existence of functionally separate COX isozymes, ruling out steroids as treatment compounds, developing polyclonal and ultimately monoclonal antibodies, sequencing and cloning human COX-1 and COX-2 DNA, and using cell-based and recombinant enzyme assays to test for selective COX-2 inhibition (hereinafter “the Project”).

[*Id.*]

**BYU RESPONSE:**

BYU admits this fact.

8. At his deposition on September 13, 2011, Mr. Fellmeth admitted that part of alleged trade secret Item 1 in Paragraph 2 of his supplemental expert report was developed during the term of the Research Agreement:

Q. Can you tell me when that item was communicated to Monsanto?

A. It was communicated in pieces. Part of it was in the initial presentation a very small part of it initial presentation by Dr. Simmons to Monsanto when he visited the first time, a much larger part in Appendix A of the research agreement; and the rest developed through the course of their collaboration and discussions.

[Transcript of Deposition of Aaron Fellmeth (“Fellmeth Dep.”) at 88:2-9.]

**BYU RESPONSE:**

BYU admits that Pfizer accurately quoted the language from Mr. Fellmeth’s deposition transcript, but that language does not address the “term of the Research Agreement.”

9. Keith Ricker was BYU’s corporate designee on the topic of BYU’s allegations regarding trade secrets in Count VIII of the First Amended Complaint. [See Transcript of BYU 30(b)(6) Deposition (representative Keith Ricker) (“BYU 30(b)(6) Dep. (Ricker)”) at 7:2-9; Notice of Taking Video Deposition of Brigham Young University Pursuant to Fed. R. Civ. P.

30(b)(6) (“BYU Rule 30(b)(6) Deposition Notice”), Topic 20.] At that deposition, Mr. Ricker testified on behalf of BYU that the alleged trade secret described in Item 1 of Paragraph 2 in Mr. Fellmeth’s supplemental expert report was “not a static trade secret” and “continued to develop” after the Research Agreement was signed:

Q. So, Mr. Ricker, starting with Exhibit- the first page of Exhibit 1073, this is the list of trade secrets that you prepared. The first one identified is the research project and plan. Can you tell me when that trade secret was created?

A. *That was not a static trade secret. That was something that Dr. Simmons probably conceived of initially -- I shouldn't say probably conceived of initially -- did conceive of initially in 1989 and continued to develop through enormous amounts of experimentation all the way leading up to the collaborative research review with Monsanto and continued to additional materials to throughout that collaboration.* So think your question was when was it developed or something like that?

Q. Yeah.

A. Starting in October '89 and continuing for a long time.

Q. Okay. And when was it first communicated to Monsanto?

A. I would say the goal of it was communicated on April 5th. The substance of how you would go about doing it was communicated after the parties started collaborating. Some of the instances of the communication of it were appendix A and some of the other things I listed here in the bullet point.

Q. Was this trade secret communicated to Monsanto before or after the research agreement was signed?

A. Before or after -- both.

[BYU 30(b)(6) Dep. (Ricker) 15 at 37:2-38:6 (emphasis added).]

**BYU RESPONSE:**

BYU admits that Pfizer has accurately quoted Mr. Ricker's testimony as a BYU-designated 30(b)(6) witness, and that he testified that some of the referenced trade secret was communicated to Monsanto after the Research Agreement was signed.

10. Dr. Simmons also testified that he continued to develop the alleged trade secret described in Item 1 of Paragraph 2 of Mr. Fellmeth's supplemental expert report during the term of the Research Agreement:

Q. Okay. So, it is, therefore, fair to say, Dr. Simmons, that neither you nor BYU had possession of the entirety of Fellmeth alleged trade secret number one as of August of 1991; correct?

A. We had parts of this, and we developed it as we went through the terms of the project, and continued to convey all of this information to them under the umbrella of the collaboration and the research agreement.

[Transcript of October 7, 2011 Deposition of Daniel Simmons ("Oct. 7, 2011 Simmons Dep.") at 227:21-228:4.]

**BYU RESPONSE:**

BYU admits that Pfizer has accurately cited the referenced deposition testimony.

11. The "project" described in Item 1 of Paragraph 2 of the Fellmeth Supplemental Report has not been patented, nor has BYU contended that the entire project should have been patented.

**BYU RESPONSE:**

BYU admits this fact.

**2. The “Compilation”**

12. Dr. Simmons testified that there is a “BYU compilation trade secret” that is “defined as the sum of the technology, information, biological materials, assistance that I gave to Monsanto.” [Oct. 7, 2011 Simmons Dep. at 160:10-14.]

**BYU RESPONSE:**

BYU admits that Dr. Simmons gave the quoted testimony, in which he was summarizing his layman’s view of a what a compilation trade secret is. BYU denies, however, that it is claiming one discrete trade secret known as its “compilation trade secret.”

13. Dr. Simmons could not identify a single document that sets out the “compilation trade secret”:

Q. BY MR. DOUGHERTY: Name one document, of all of those that you listed, that was sent to Monsanto that sets out the compilation trade secret.

THE WITNESS: As I said, it was the summation of our interactions. So, one document, by definition, could not show that.

Q. BY MR. DOUGHERTY: In fact, there is no document, until you were years into this litigation, that actually attempts to define a compilation trade secret; isn’t that right, Dr. Simmons?

A. I don’t think that’s right. I am not sure we ever had any as I said, the compilation is our interaction. That is what the whole program, project, collaboration that we were going toward in developing a selective COX-2 NSAID.

[*Id.* at 184:15-185:4.]

**BYU RESPONSE:**

BYU admits that Pfizer accurately quoted the transcript of Dr. Simmons’s testimony.

14. Dr. Simmons admitted that he developed components of the “compilation trade secret” after the Research Agreement began:

QUESTION: So the compilation—the compilation trade secret, components of it which you say you had in April of 1991, but other components of it you had during the term of the research agreement; correct?”

THE WITNESS: Other components I developed, my laboratory developed during the terms of-- during the terms of the research agreement; yes.

[*Id.* at 192:17-24.]

**BYU RESPONSE:**

BYU admits that Pfizer accurately quoted the deposition transcript, but denies it is claiming one discrete “compilation trade secret.”

15. Dr. Simmons admitted that he delivered components of the “compilation trade secret” to Monsanto after the Research Agreement had been terminated:

Q. BY MR. DOUGHERTY: And what was the last piece necessary for that compilation to be complete?

A. Well, as I said, the compilation is everything in the collaboration. And continued to provide them information prior to providing anyone else that information in July, and then my memory sparked that

Q. I’m sorry, can you just say the year so we don’t have to come back?

A. I’m sorry. July of 1992.

Q. Um-hmm.

A. And then my memory seemed to recall that there may have been another conveyance of information perhaps in the form of a report that occurred after that time.

[*Id.* at 192:25-193:14; *see also Id.* at 186:3-7, 186:21-187:4.]

**BYU RESPONSE:**

BYU admits that Pfizer accurately quoted the deposition transcript, but denies that it is claiming one discrete “compilation trade secret.”

16. The “compilation trade secret” has not been patented, nor has BYU contended that it should have been patented. [*See id.* at 185:12-21.]

**BYU RESPONSE:**

This statement is based on the apparent misapprehension that BYU is claiming a separate “compilation trade secret,” so it can’t be admitted or denied. BYU has, however, asserted that certain combinations of materials and information, which could be collectively viewed as compilation trade secrets, should have been patented. *See* First Amended Complaint ¶ 107.

**BYU’S STATEMENT OF FACTS<sup>9</sup>**

**A. BYU Adequately Disclosed Its Compilation Trade Secret Claim In This Litigation.**

1. Count VIII of BYU’s First Amended Complaint asserts a cause of action for violation of Utah’s Uniform Trade Secret Act, Utah Code Ann. § 13-24-2, et seq.

2. Pfizer’s Interrogatory No. 8 asked BYU to:

State fully and completely all factual and legal bases for your allegation that Defendants violated the Uniform Trade Secret Act...

3. In its verified response to Pfizer’s Interrogatory No. 8, BYU disclosed that the “trade secrets conveyed to Monsanto” took two forms: “First, the entire Project constituted a trade secret incorporating the confidential information BYU transmitted to Monsanto to support the Project,” whose aim was “to develop nonsteroidal anti-inflammatory drugs (‘NSAIDs’) that would selectively inhibit COX-2 (or COX-1).<sup>10</sup>

4. As BYU elaborated:

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<sup>9</sup> All exhibits in support of this Opposition have been consolidated with Plaintiffs’ exhibits in support of concurrently filed oppositions.

<sup>10</sup> Pls. Amd. 2<sup>nd</sup> Supp. Resp. to Defs. Interr. No. 8, 10 Dec 08, p. 3, Ex. 188.



Monsanto could not have obtained the totality of BYU's trade secrets from any other source at the time it was provided. Monsanto derived economic value from this collective body of information because it was not available in a comprehensive form from any other source—even if certain individual components may have later become publicly available.<sup>11</sup>

5. Second, “the individual components of information and tools BYU provided to Monsanto in support of and as part of the Project also constitute individual trade secrets that each possessed independent economic value from not being publicly known at the time BYU provided them to Monsanto.”<sup>12</sup> At pages 31-72 of BYU's response to Pfizer Interrogatory No. 8, BYU also listed and described those individual trade secrets, including information about where those trade secrets were memorialized in the documents.<sup>13</sup>

6. As the preface to that list states:

BYU provided Monsanto access to the totality of scientific data and biological tools it had developed that would assist in the discovery of a COX-2 selective NSAID. BYU provided no one else with this collective body of scientific data and biological tools. This collective body of scientific data and biological tools is, itself, a trade secret.<sup>14</sup>

7. BYU expert Aaron Fellmeth also summarized 70 discrete trade secrets that BYU communicated to Monsanto.<sup>15</sup> In addition to the individual trade secrets, Mr. Fellmeth also stated: “Collectively this information constitutes a trade secret.”<sup>16</sup>

8. The very first trade secret Mr. Fellmeth identified was:

A research project and plan for the selection, testing, and modifying of nonsteroidal anti-inflammatory drugs for COX-2 selectivity by establishing the existence of functionally separate

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<sup>11</sup> *Id.*

<sup>12</sup> *Id.* at p. 4.

<sup>13</sup> *Id.* at pp. 31-72.

<sup>14</sup> *Id.* at p. 31.

<sup>15</sup> A. Fellmeth Supp. Expert Rpt., 10 Jun 11, pp. 2-4, Ex. 206.

<sup>16</sup> *Id.* at 2.

COX isozymes, ruling out steroids as treatment compounds, developing polyclonal and ultimately monoclonal antibodies, sequencing and cloning human COX-1 and COX-2 DNA, and using cell-based and recombinant enzyme assays to test for selective COX-2 inhibition (hereinafter “the Project”).

9. A similar list was given to Monsanto, as compiled by Mr. Keith Ricker, BYU’s 30(b)(6) witness on trade secrets.<sup>17</sup>

10. These trade secrets were sufficiently well identified that, in the expert report of Defendants’ expert Joseph Mancini, he was able to identify and describe each of them separately in a chart that purported to show that each trade secret had been publicly disclosed or made readily available.<sup>18</sup>

11. Pfizer also took the opportunity to depose BYU experts Mr. Fellmeth and Dr. Bell, as well as Mr. Ricker and Dr. Simmons himself, asking each of them numerous questions pertaining to BYU’s trade secrets.<sup>19</sup>

**B. In 1989, Dr. Simmons Discovered A Second COX Enzyme, And Was The First Person To Have the Vision Of Designing NSAIDs To Selectively Inhibit That Enzyme.**

12. This case deals with what have been called non-steroidal anti-inflammatory drugs or “NSAIDs.” Traditional NSAIDs like aspirin and ibuprofen have been used for years to treat inflammation, pain and fever.<sup>20</sup> In 1990, estimated worldwide sales of NSAIDs were \$5.3 billion.<sup>21</sup>

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<sup>17</sup> K. Ricker, “Substance and Identity of BYU’s Trade Secrets,” marked as part of Ex. 1073 to Mr. Ricker’s 2 Jun 11 deposition, Ex. 190.

<sup>18</sup> J. Mancini Expert Rpt., 24 Jul 11, at Appdx. G, Ex. 191.

<sup>19</sup> K. Ricker Dep., 2-3 Jun 11, Ex. 192; A. Fellmeth Dep., 13 Sep 11, Ex. 193; R. Bell Dep., 29 Sep 11, Ex. 138; D. Simmons Dep., 7-8 Oct 11, Ex. 4.

<sup>20</sup> R. Bell Expert Rpt., 18 Feb 11, ¶¶ 7-8, Ex. 47; Cyclooxygenase-2 Inhibitor Project, 9 Sep 92, BYU-PFE 042354-359 at 354, Ex. 139.

<sup>21</sup> P. Isakson Witness Statement, 23 Aug 99, ¶ 3, Ex. 99.

13. The key to how aspirin and other NSAIDs work is an enzyme commonly called cyclooxygenase or “COX.”<sup>22</sup> The COX enzyme produces molecules called prostaglandins, which are important in inflammation and pain; NSAIDs work by preventing COX from producing prostaglandins.<sup>23</sup> A major problem of traditional NSAIDs, however, is that they induce “gastric side effects including potentially fatal stomach ulcers.”<sup>24</sup>

14. As Monsanto has acknowledged:

For many years it was thought that COX was a single enzyme present constitutively in most cells and that inhibition of this enzyme would lead to decreased production of unwanted PGs [prostaglandins], e.g. in inflamed tissue, as well as beneficial PGs produced in the stomach, kidney and perhaps elsewhere.<sup>25</sup>

15. In 1989, Dr. Simmons at BYU discovered and cloned a second COX gene, now called “COX-2.”<sup>26</sup> Studies show that this second isoform of COX, “COX-2,” is what actually induces the prostaglandins that caused pain and inflammation, whereas the first type of COX (now called “COX-1”), is a “constitutive form present in tissues such as gut and kidney.”<sup>27</sup> COX-1 produces prostaglandins “that are necessary for normal physiological function.”<sup>28</sup>

16. The Defendants later acknowledged the significance of the discovery of COX-2:

The discovery of COX-2 represents perhaps the greatest potential breakthrough in medicine and certainly the greatest breakthrough in the treatment of arthritis and pain.<sup>29</sup>

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<sup>22</sup> R. Bell Expert Rpt., 18 Feb 11, Ex. 47 at ¶¶ 7-8.

<sup>23</sup> *Id.* at ¶¶ 7-8; S. Prescott Expert Rpt., 18 Feb 11, Ex. 33 at ¶ 1.

<sup>24</sup> P. Isakson Witness Statement, 23 Aug 99, Ex. 99 at ¶ 3.

<sup>25</sup> Cyclooxygenase-2 Inhibitor Project, 9 Sep 92, Ex. 139 at BYU-PFE 042355.

<sup>26</sup> Ltr. to E. Woolley from D. Simmons, 19 Oct 89, BYU-12-0511-528, Ex. 10.

<sup>27</sup> Cyclooxygenase-2 Inhibitor Project, 9 Sep 92, Ex. 139 at BYU-PFE 042355.

<sup>28</sup> Monsanto Briefing Document For SC-58635, 15 Jul 97, BYU-PFE 666868-906 at 872, Ex. 194.

<sup>29</sup> *Id.*

17. Dr. Simmons's 1989 discovery of COX-2 was the culmination of years of study, training and research.<sup>30</sup> From 1978 through 1986, Dr. Simmons was trained in pharmacology, biochemistry, and molecular biology, including the cloning and characterization of inducible genes.<sup>31</sup> By 1982, for example, Dr. Simmons was involved in the cloning and characterization of a molecule that had not previously been cloned, and learned "how to clone, identify and sequence inducible mRNAs."<sup>32</sup> This was a skill that was rare at that time and "required the mastery of a number of different techniques to work with and manipulate mRNAs, cDNAs, and genes."<sup>33</sup> That and other skills that he learned put Dr. Simmons in a unique position to do his later work relating to cyclooxygenase.<sup>34</sup>

18. From 1986 until early 1989, Dr. Simmons worked at Harvard University in the laboratory of Raymond L. Erikson, the American Cancer Society Professor of Cellular and Development Biology.<sup>35</sup> His work focused on searching for inducible genes that might be involved with cancer, and led to his cloning of what he initially called "CEF-147," but which, when he got to BYU, he identified as COX-2.<sup>36</sup>

19. As Pfizer expert Dr. Tim Hla has testified, the experimental process of cloning a gene is "tedious" and "difficult," and takes "intensive" work "for quite some time."<sup>37</sup>

20. During Dr. Simmons's lengthy process in isolating and cloning CEF-147, or COX-2, he:

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<sup>30</sup> D. Simmons Amended and Supp. Expert Rpt., 10 Jun 11, ¶¶ 4-37, Ex. 57.

<sup>31</sup> *Id.* at ¶ 2.

<sup>32</sup> *Id.* at ¶¶ 21-25.

<sup>33</sup> *Id.* at ¶ 25.

<sup>34</sup> *Id.* at ¶ 25.

<sup>35</sup> *Id.* at ¶ 53.

<sup>36</sup> *Id.* at ¶ 38.

<sup>37</sup> T. Hla Dep., *Univ. of Rochester v. Searle*, 16 Jan 03, 58:3-59, Ex. 142.

- Made cDNA “libraries,” which are collections of the different DNA sequences in a cell, in order to isolate and identify DNA clones.<sup>38</sup>
- Isolated the total pool of inducible genes from which he ultimately isolated COX-2<sup>39</sup>
- Made antibodies, including “every step in the multi-step procedure for making the antigen,” from “injection to characterizing the resulting serum for titer and cross-reactivity.”<sup>40</sup>
- Prepared probes and “screened,” by various “novel and laborious methods,” the cDNA libraries he had constructed, in order to identify a variety of important genes involved in cancer and in other cellular processes.<sup>41</sup>
- Obtained “hundreds of clones that had tested positive” through the screening process, then placed them into groups to determine whether any of the clones were related to or the same as other of the clones that had been found.<sup>42</sup>
- In Dr. Simmons’s words:  
  
“Group placement required many steps and many techniques, including plaque purifications phage isolation, DNA purification, restriction digestions, Southern blotting, radioactive probe labeling, cross-hybridization analysis and Northern blotting.”<sup>43</sup>
- Found a group of 12 genes that were induced or activated by a cancer-causing virus in an “immediate early” fashion.<sup>44</sup>
- Tested induction of the 12 clones using various inducers, including serum (blood serum).<sup>45</sup>
- Partially “sequenced” the clones that had been isolated to learn their nucleic acid or protein sequences.<sup>46</sup> In this process he identified genes that were completely unknown to science.<sup>47</sup>

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<sup>38</sup> D. Simmons Amended and Supp. Expert Rpt., 10 Jun 11, Ex. 57 at ¶¶ 39-41.

<sup>39</sup> *Id.* at ¶ 45.

<sup>40</sup> *Id.* at ¶ 58.

<sup>41</sup> *Id.* at ¶¶ 56, 61-68.

<sup>42</sup> *Id.* at ¶ 69.

<sup>43</sup> *Id.* at ¶ 70.

<sup>44</sup> *Id.* at ¶ 73.

<sup>45</sup> *Id.* at ¶¶ 81-83.

<sup>46</sup> *Id.* at ¶¶ 93-94.

<sup>47</sup> *Id.* at ¶ 94.

- Determined the full-length sequence of a full-length clone, which was a “laborious process taking many steps.”<sup>48</sup>
- Determined the sequence of a COX-2 cDNA by the fall of 1989.<sup>49</sup>

21. Dr. Simmons understood at the time that, as the target for NSAIDs, the COX enzyme was “the foundation of a multibillion dollar industry.”<sup>50</sup> Dr. Simmons also understood that his discovery raised the possibility of designing NSAIDs that would selectively block only the COX-2 enzyme, thus not blocking the helpful secretions that protected the lining of the stomach and other organs.<sup>51</sup>

22. To document his discovery, Dr. Simmons wrote a notarized letter, dated 19 October 1989, to the Chairman of BYU’s Chemistry Department. In that letter Dr. Simmons said:

By studying the structure of both the growth and normal synthetases [COX-2 and COX-1] we may be able to **rationally design drugs that selectively inhibit one or the other and thus reduce unwanted side effects.**<sup>52</sup>

23. This statement by Dr. Simmons is the first written statement proposing the idea of selectively inhibiting COX-1 versus COX-2 for the purposes of designing an NSAID that would reduce unwanted side effects.<sup>53</sup> Pfizer’s expert witness was not aware of any other written statement to that effect in the 1989 to 1991 time period.<sup>54</sup>

24. Although Monsanto’s Dr. Needleman had previously hypothesized the existence of a “second pool” of COX, “pool” is not a scientific term, and “you could come up with

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<sup>48</sup> *Id.* at ¶¶ 97-103.

<sup>49</sup> *Id.* at ¶¶ 130-131.

<sup>50</sup> Ltr. to E. Woolley from D. Simmons, 19 Oct 89, Ex. 10 at BYU-12-0513.

<sup>51</sup> *Id.*

<sup>52</sup> *Id.* (emphasis added).

<sup>53</sup> T. Hla Dep., 21 Sep 11, 192:9-194:7, Ex. 126.

<sup>54</sup> *Id.* at 192:9-194:7.

different conclusions” regarding the cause of these different “pools.”<sup>55</sup> Prior to Dr. Simmons’s association with Monsanto, “Dr. Needleman had not resolved this pool theory to determine what was really going on.”<sup>56</sup> And as Pfizer’s expert molecular biologist testified, in order to determine what was really going on, “you need to clone the gene to completely identify that you have a second form of the enzyme,” so “when the COX-2 gene was cloned, it showed that there was a second form of the enzyme, and that was the **definitive evidence.**”<sup>57</sup>

25. As Monsanto’s expert also testified, Dr. Simmons was the first one to clone a COX-2 cDNA.<sup>58</sup>

**C. Prior To 1992, Pharmaceutical Companies Were Not Looking For COX-2 Selective Or Gastric-Sparing NSAIDs, Hence The NSAID Market Was Stagnant.**

26. Because of the large number of NSAIDs already on the market, all of which had serious side effects, NSAID research was a “relatively unproductive area of research by the 1980s.”<sup>59</sup> Most pharmaceutical companies had only modest interest in expending the resources to identify, develop, and market additional NSAIDs, because it was understood that any new NSAID would have the same serious side effects as existing NSAIDs.<sup>60</sup>

27. By 1990, without knowledge of Dr. Simmons’s discovery, the majority of COX researchers—having looked for a second COX gene without success—concluded that there was only one COX gene and one COX enzyme.<sup>61</sup> For example, in 1990, one prominent researcher, Dr. William Smith from Michigan State University, published a paper expressing his conclusion

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<sup>55</sup> J. Mancini Dep., 7 Nov 11, Ex. 32 at 347:3-349:12.

<sup>56</sup> *Id.* at 347:3-349:12.

<sup>57</sup> *Id.* at 347:3-349:12 (emphasis added).

<sup>58</sup> *Id.* at 350:3-9.

<sup>59</sup> R. Bell Expert Rpt., 18 Feb 11, Ex. 47 at ¶¶ 16-18.

<sup>60</sup> *Id.* at ¶¶ 16-18.

<sup>61</sup> *Id.* at ¶ 11.

that there was only a single COX gene.<sup>62</sup> The “conclusion that there was only one COX gene was generally accepted among COX researchers and the pharmaceutical industry.”<sup>63</sup>

28. For example, the notes of Monsanto’s Dr. Seibert, taken at a presentation given by a scientist discussing cyclooxygenase at a May 1990 prostaglandin conference in Florence, state: “looks like only 1 gene.”<sup>64</sup>

29. Indeed, for a period of at least 29 months, beginning in late 1988 and continuing through April 1991 (when Dr. Simmons shared his finding with Monsanto), Monsanto’s Dr. Karen Seibert had herself been trying to isolate a second form of COX, but had not succeeded.<sup>65</sup> As Dr. Seibert testified, prior to Dr. Simmons presenting his ideas to Monsanto, Monsanto “had not yet resolved the existence of the two-cyclooxygenase system.”<sup>66</sup>

30. Monsanto did recognize, however, as expressed in a February 1991 e-mail from Monsanto’s Roger Weigand to Dr. Phil Needleman, that “**if a second, inducible, COX exists it would be a prime candidate as a drug target,**” and if so, “there’s a big science payoff just waiting for the taking.”<sup>67</sup>

31. But as Pfizer expert Dr. Mancini testified, he is not aware of any pharmaceutical companies by 1991 that were involved in efforts to find a COX-2 selective drug, other than Monsanto after its association with Dr. Simmons.<sup>68</sup>

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<sup>62</sup> S. Prescott Expert Rpt., 18 Feb 11, Ex. 33 at 8; *see also*, Smith, W.L., et al., *Molecular Basis for the Inhibition of Prostanoid Biosynthesis by Nonsteroidal Anti-inflammatory Agents*, *Stroke*, Vol. 21, No. 12 (Dec. 1990), Ex. 94.

<sup>63</sup> R. Bell Expert Rpt., 18 Feb 11, Ex. 47 at ¶ 15.

<sup>64</sup> K. Seibert Florence Conference Notes, 28 May-11 Jun 90, PFC00678266-327 at 293, Ex. 195.

<sup>65</sup> K. Seibert Dep., 1-3 Jun 10, 318:24-321:3, Ex. 3.

<sup>66</sup> *Id.* at 817:13-19.

<sup>67</sup> Email to P. Needleman from R. Wiegand, 15 Feb 91, S01433453, Ex. 96 (emphasis added).

<sup>68</sup> J. Mancini Dep., 7 Nov 11, Ex. 32 at 56:8-57:1.



**D. After Discovering And Cloning A Second COX Gene, Dr. Simmons, Before Collaborating With Monsanto, Did Further Research And Experiments To Develop His Vision, Plan And Tools To Select, Test, And Modify COX-2 Selective NSAIDs.**

32. As noted, by October 1989, Dr. Simmons had discovered the existence of a separate cyclooxygenase gene, “COX-2,” and had partially cloned a chicken COX-2 cDNA.<sup>69</sup>

33. Prior to sharing his findings with anyone outside of BYU, however, he continued his research on COX 1 and COX-2. The evidence shows that by February of 1991, Dr. Simmons and his laboratory had:

- Tested some traditional NSAIDS to see if they inhibited COX-2.<sup>70</sup>
- Tested some traditional NSAIDs for their ability to kill cancer cells that contain COX-2, versus normal cells lacking COX-2.<sup>71</sup>
- Done the first testing using a cell system characterized for COX-2 expression.<sup>72</sup>
- Determined how COX-1 differed from COX-2.<sup>73</sup>
- Constructed and sequenced a full-length COX-2 clone.<sup>74</sup>
- Constructed DNA plasmids for performing RNA protection assays, sometimes called “nuclease protection assays,” the first time this technique was used to measure the expression of COX-2 mRNA.<sup>75</sup> (Monsanto later used this same technique, using Dr. Simmons’s mouse COX-1 and COX-2 cDNA clones and sequences.)
- Cloned chicken COX-2 into an expression vector called PET-3, and then used the vector to cause bacteria to synthesize significant amounts of chicken COX-2 protein.<sup>76</sup>

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<sup>69</sup> Ltr. to E. Woolley from D. Simmons, 19 Oct 89, BYU-12-0511, Ex. 10.

<sup>70</sup> D. Simmons Amended and Supp. Expert Rpt., 10 Jun 11, Ex. 57 at ¶ 149.

<sup>71</sup> *Id.* at ¶ 154.

<sup>72</sup> *Id.* at ¶ 158.

<sup>73</sup> *Id.* at ¶¶ 164-172.

<sup>74</sup> *Id.* at ¶¶ 180-181, 286.

<sup>75</sup> *Id.* at ¶ 184.

<sup>76</sup> *Id.* at ¶ 188.

- Prepared purified COX-2 protein for the first time and produced for the first time an anti-COX-2 antibody.<sup>77</sup>
- Did the first immunoprecipitation of COX-2 protein using an anti-COX-2 antibody.<sup>78</sup>
- Examined the expression of COX-2 in a variety of tissues in chicken, which showed that little COX-2 is found constitutively in the body.<sup>79</sup>
- Cloned mouse COX-1 and mouse COX-2 and compared their sequences side-by-side.<sup>80</sup> By 19 January 1991, Dr. Simmons's lab had the only matched pair of COX-1 and COX-2 clones from a single animal species in the world.<sup>81</sup>
- Examined the expression of mouse COX-1 and COX-2 in tissues and cells.<sup>82</sup>

34. In addition to the above, Dr. Simmons's expert report gives many other examples of COX-related research, tests and tools that his laboratory conducted, made or further developed between 1989 and February 1991.<sup>83</sup>

35. In summary, by early 1991, in Dr. Simmons's words:

It is my opinion, therefore, that when I went to the Monsanto laboratory in April [1991] that my laboratory, and only my laboratory, was in possession of much of this knowledge regarding COX-2 and only I was in possession of many of the reagents needed to investigate COX-2 in a pharmaceutical setting including, but not limited to, being the sole possessor of COX-1 and COX-2 clones from the same species and characterized anti-COX-2 antibody as well as purified COX-2 protein.<sup>84</sup>

36. In addition to Dr. Simmons's expert report in this case, documents written by Dr. Simmons at the time also show that, by early 1991, Simmons had developed a specific plan for

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<sup>77</sup> *Id.* at ¶¶ 190-192.

<sup>78</sup> *Id.* at ¶ 192.

<sup>79</sup> *Id.* at ¶¶ 233-236.

<sup>80</sup> *Id.* at ¶¶ 317-320, 339-348.

<sup>81</sup> *Id.* at ¶ 342.

<sup>82</sup> *Id.* at ¶¶ 205-210, 313-315.

<sup>83</sup> *Id.* at ¶¶ 180-374.

<sup>84</sup> *Id.* at p. 87, ¶ 374.

selecting, testing and modifying NSAIDS through the use of his COX-1 and COX-2 biological materials and information.<sup>85</sup>

**E. BYU and Dr. Simmons Took Reasonable Steps To Preserve The Confidentiality of Their COX-2 Discoveries And Research.**

37. Despite his discovery of COX-2 in 1989 and the further research relating to that discovery, Dr. Simmons did not publish anything about his work until April 1991.<sup>86</sup> And although Dr. Simmons's April 1991 paper disclosed his cloning of chicken COX-2, the paper did not disclose his compilation trade secret generally or important elements of that trade secret.<sup>87</sup> For example, by the time of his April 1991 publication, Dr. Simmons had also identified the sequence of mouse COX-2 and had developed his own clones of mouse COX-1 and mouse COX-2, but the April 1991 article did not disclose those discoveries.<sup>88</sup>

38. At BYU itself, Dr. Simmons's laboratory, all rooms in which experiments were conducted, and the trade secrets developed therein were protected by a locked door, unless either Dr. Simmons or one of his employees was inside.<sup>89</sup> BYU did not distribute keys fitting the locks of the doors except to BYU biochemistry professors having offices on the same floor as Dr. Simmons's laboratory, Dr. Simmons's graduate and honors thesis students, and BYU custodial employees.<sup>90</sup>

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<sup>85</sup> Ltr. to E. Wooley from D. Simmons, 19 Oct 89, BYU-12-0511-528, Ex. 10; D. Simmons NIH Grant Application, 27 Jan 91, BYU-12-1087-119, Ex. 103, Research Proposal, 5 Apr 91, BYU-11-2376-378, Ex. 11; Research Agreement, Appdx. A, 1 Aug 91, BYU-11-0111-127, Ex. 9.

<sup>86</sup> Xie, et al, *Expression of a Mitogen-Responsive Gene Encoding Prostaglandin Synthase is Regulated by mRNA Splicing*, Proc. Natl. Acad. Sci. USA Vol. 88 (1991), BYU-18-4391-395, Ex. 54.

<sup>87</sup> *Id.*

<sup>88</sup> *Id.*

<sup>89</sup> Pls. 2<sup>nd</sup> Supp. Resp. to Defs. Interr. No. 8, 10 Dec 08, p. 10, Ex. 188.

<sup>90</sup> *Id.*

39. Further, Dr. Simmons's employees, specifically Jeffrey Chipman, Gary Evett, and Weilin Xie, understood from their discussions and interaction with Dr. Simmons that the work performed in the laboratory, including the work that yielded the trade secrets at issue, was confidential and was not to be communicated outside the laboratory.<sup>91</sup> The laboratory employees were particularly concerned about confidentiality because they did not want competing laboratories to get the trade secret information.<sup>92</sup>

40. For example, Dr. Xie was asked if Dr. Simmons had discussions with him concerning the confidentiality of the work, to which Dr. Xie replied:

Oh, yeah. That was very clear. And we work in very competitive work. And it's really, the confidentiality was – Dr. Simmons made it clear to me the project you work with and you report to me, we discuss it. And so that was very clear.<sup>93</sup>

41. Additionally, in 1991, when Dr. Simmons's employee, Jeffrey Chipman, submitted his undergraduate thesis to satisfy graduation requirements, he understood that it needed to stay confidential; Chipman did not make his thesis publicly available.<sup>94</sup> BYU did not make the thesis available in its library until 1993, well after Monsanto terminated the collaboration with BYU.<sup>95</sup>

42. Similarly, after Monsanto terminated the Research Agreement with BYU, Weilin Xie obtained employment with Dr. Harvey Herschman but did not communicate the trade secrets he learned in working with Dr. Simmons in his laboratory.<sup>96</sup>

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<sup>91</sup> *Id.*

<sup>92</sup> *Id.*

<sup>93</sup> W. Xie Dep., 27 Mar 09, Ex. 82 at 21:14-21, 22:3-34:20.

<sup>94</sup> Pls. 2<sup>nd</sup> Supp. Resp. to Defs. Interr. No. 8, 10 Dec 08, Ex. 188 at p. 10.

<sup>95</sup> *Id.* at p. 11.

<sup>96</sup> *Id.*

43. Gary Evett also kept the trade secrets that he learned through his work with Dr. Simmons confidential during and after his employment with Dr. Simmons.<sup>97</sup>

**F. Dr. Simmons Shared With Monsanto His COX-2 Discoveries and Vision And Plan For Developing COX-2 Selective NSAIDs, Along With Biological Reagents And Information On How To Use Them.**

44. Beginning on 5 April 1991 and continuing up to 1 August 1991, the “effective date” of the Research Agreement, Dr. Simmons shared with Monsanto not only his specific plans for the selection, testing, and modifying of compounds to find a COX-2 selective drug, but also the COX-related biological materials that he had developed before 5 April 1991, as well as those that he developed or refined after that date, and a great deal of practical information for using those materials in the search for COX-2 selective NSAIDs.<sup>98</sup>

45. Much of the confidential information that Dr. Simmons shared with Monsanto was shared via approximately 60 telephone calls he made to Monsanto scientists, including to (314) 362-2565, the phone number for Dr. Needleman’s laboratory at Washington University (where Dr. Seibert and Dr. Masferrer were located until late 1991).<sup>99</sup> This number appears to have been shared by at least Dr. Masferrer, Dr. Seibert, and Kathy Leahy.<sup>100</sup> Dr. Simmons also shared confidential information with Monsanto through an approximately equal number of phone calls that Monsanto scientists made to him during the same period.<sup>101</sup>

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<sup>97</sup> *Id.*

<sup>98</sup> D. Simmons Amended and Supp. Expert Rpt., 10 Jun 11, Ex. 57 at ¶¶ 37-676 contains a detailed discussion of the materials and information Dr. Simmons provided to Monsanto during this period, and Monsanto’s use of those materials and information.

<sup>99</sup> D. Simmons Decl., 17 Jun 11, Ex. 5 at ¶ 15; D. Simmons laboratory telephone logs, BYU-01-1290-404, Ex. 16.

<sup>100</sup> D. Simmons Decl., 17 Jun 11, Ex. 5 at ¶ 15.

<sup>101</sup> *Id.* at ¶ 15.

46. During these phone calls, Dr. Simmons disclosed much additional trade secret Confidential Information to Monsanto through Dr. Seibert and Dr. Masferrer, and occasionally Dr. Needleman.<sup>102</sup>

47. As BYU expert Dr. Bell has opined:

The set of concepts and reagents given Monsanto by Simmons in 1991 must be taken as a whole, **as it constituted a unified plan, supporting data, and unique reagents.** Importantly, to my knowledge, no one anywhere prior to March of 1992 had laid out disclosed a plan for finding COX-2 selective NSAIDs. As I have examined this package as a whole, I see that it gave a large advantage to Monsanto over its industrial competitors. **No other company had this set in 1991, and only Merck had much of it by mid-1993.**<sup>103</sup>

**1. Dr. Simmons's 5 April 1991 Presentation At Monsanto.**

48. On 5 April 1991, Dr. Simmons, at Monsanto's request, presented a seminar to Monsanto scientists at Monsanto during which he discussed his discovery of COX-2 and his cloning of COX-2 in chicken and mouse.<sup>104</sup> He also explained the overall objective of his plan in light of the discovery of an additional COX gene and enzyme:

Pharmaceutically, this multiplicity of enzymes may be exploited to design more selective inhibitors of PGHS [COX].<sup>105</sup>

49. On 5 April 1991 also, Dr. Simmons gave Monsanto's Dr. Needleman a Research Proposal.<sup>106</sup> That proposal disclosed Simmons's finding of "multiple PGHS enzymes" (*i.e.* COX-1 and COX-2) that "raise[d] significant questions relevant to the pharmaceutical industry," including whether NSAIDS "show selective inhibition of isoenzymic forms of [COX]."<sup>107</sup>

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<sup>102</sup> D. Simmons Decl., 1 Jun 09, Ex. 12 at ¶ 23.

<sup>103</sup> R. Bell Rebuttal Expert Rpt., 26 Aug 11, ¶ 49, Ex. 196 (emphasis added).

<sup>104</sup> Pls. Amd. 2<sup>nd</sup> Supp. Resp. to Defs. Interr. No. 8, 10 Dec 08, Ex. 188 at p. 6.

<sup>105</sup> D. Simmons Conclusions Slide, 3 Apr 91, BYU-10-0676, Ex. 197.

<sup>106</sup> Research Proposal, 5 Apr 91, BYU-11-2376-378, Ex. 11.

<sup>107</sup> *Id.* at BYU-11-2377.

50. The Research Proposal also disclosed that Dr. Simmons's had "cloned and partially characterized" a COX-2 cDNA in chicken and mouse, and disclosed details about how the COX-2 gene functioned.<sup>108</sup>

51. The Research Proposal also stated that BYU was seeking a collaboration with a pharmaceutical company interested in pursuing the drug-related applications of our work. Our first interest is the interaction of NSAIDS with PGHS isoenzymes.<sup>109</sup>

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In addition to funding, we would like to establish a productive interaction with biochemists and organic chemists within the pharmaceutical company who could provide prostaglandins and NSAIDs for testing as well as participate in discourse about the work we are pursuing.<sup>110</sup>

**2. Monsanto Prepares A Research Agreement With Confidentiality Provisions.**

52. On 11 April 1991, Monsanto patent lawyer Larry Swaney sent Dr. Simmons a draft Research Agreement for BYU's review and approval.<sup>111</sup>

53. Paragraph 4.1 of the draft Research Agreement contained confidentiality provisions that protected as confidential all:

proprietary information, including information relating to transformed cells, genes, transformation vectors, transformation, selection and regeneration procedures, media formulations, chemicals, DNA sequences, and probes....<sup>112</sup>

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<sup>108</sup> *Id.*

<sup>109</sup> *Id.*

<sup>110</sup> *Id.* at BYU-11-2378.

<sup>111</sup> Ltr. to D. Simmons from L.R. Swaney, with attached draft of Research Agreement, 11 Apr 91, S00660056-069, Ex. 14.

<sup>112</sup> *Id.* at ¶ 4.1.

54. Under the Research Agreement, the parties agreed that confidential information would be used “only as provided for in this Agreement,” and agreed not to use or disclose such information “in any other manner.”<sup>113</sup>

55. The confidentiality provisions in the first draft agreement remained the same in the final, signed Research Agreement.<sup>114</sup> Because, among other reasons, the confidentiality provisions became effective “from the date of disclosure,” the Court has held that information that BYU or Dr. Simmons shared with Monsanto was subject to the Research Agreement’s confidentiality provisions, even if the information was shared prior to the Research Agreement.<sup>115</sup>

**3. Following The April 1991 Scientific Conference, Dr. Simmons Sends COX-Related Biological Reagents To Monsanto.**

56. In late April 1991, Dr. Simmons attended a scientific “FASEB” conference in Atlanta, Georgia.<sup>116</sup> (“FASEB” is the Federation of American Societies for Experimental Biology.)

57. While at the FASEB conference, Dr. Simmons also met again with Monsanto scientists Drs. Seibert and Masferrer.<sup>117</sup> They expressed an interest in beginning their scientific collaboration immediately, and asked Dr. Simmons to send them his COX-2 clone and other biological materials.<sup>118</sup> Pursuant to their request, and understanding that his materials would be confidential,<sup>119</sup> Dr. Simmons did so on 29 April 1991, sending them his mouse COX-1 and

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<sup>113</sup> *Id.*

<sup>114</sup> Research Agreement, 1 Aug 91, BYU-11-0111-127, Ex. 9 at ¶ 4.1.

<sup>115</sup> Mem. Dec. and Order, 30 Sep 09, Dkt. 302.

<sup>116</sup> D. Simmons Dep., 20-21 Apr 09, Ex. 1 at 283:14-284:17; 289:10-19.

<sup>117</sup> *Id.* at 283:14-284:17.

<sup>118</sup> *Id.*

<sup>119</sup> Pls. 2<sup>nd</sup> Supp. Resp. to Defs. Interr. No. 8, 10 Dec 08, Ex. 188 at p. 10.



mouse COX-2 cDNAs, his chicken COX-2 antibodies, and information about the use of such.<sup>120</sup> Dr. Simmons later sent Monsanto the nucleotide sequences and restriction maps for his mCOX-1 and mCOX-2 cDNAs.<sup>121</sup>

58. At that time, and throughout 1991, Dr. Simmons had the only set in the world of COX-1 and COX-2 cDNAs from the same mammalian species.<sup>122</sup> In addition, in the words of BYU expert Dr. Dellaria:

At that time no other research group, either academic or industrial, had access to the unique combination of Dr. Simmons clones, antibodies, research data, expert advice and project.<sup>123</sup>

**4. From May Through July 1991, Dr. Simmons Provides Monsanto With Additional Scientific Materials And Information.**

59. On 23 May 1991, Simmons also provided Monsanto with a copy of his confidential 27 January 1991 NIH grant application.<sup>124</sup> The NIH proposal contained detailed information about the role of COX-2 in cancer and the potential of COX-2 as a target for anti-cancer therapy.<sup>125</sup>

60. On 6 June 1991, Dr. Simmons faxed to Drs. Seibert and Masferrer's Washington University labs a document showing a side-by-side comparison of the GenBank nucleotide sequences for murine COX-1 with his nucleotide sequence for COX-2.<sup>126</sup> "GenBank" is a

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<sup>120</sup> Ltr. from D. Simmons to K. Seibert and J. Masferrer, 29 Apr 91, BYU-PFE 059332, Ex. 15.

<sup>121</sup> Expert Rebuttal Report, D. Simmons, 26 Aug 11, Ex. 161 at ¶ 95 and App. A, p. 5.

<sup>122</sup> K. Seibert Dep., 1-3 Jun 10, Ex. 3 at 359:23-360:14; D. Simmons Amended and Supp. Expert Rpt., 10 Jun 11, Ex. 57 at ¶ 342.

<sup>123</sup> J. Dellaria Expert Rpt., 18 Feb 11, Ex. 198 at ¶ 5.

<sup>124</sup> Ltr. to P. Needleman from D. Simmons, 23 May 91, BYU-05-8934, Ex. 102.

<sup>125</sup> *Id.*

<sup>126</sup> Fax to K. Seibert from D. Simmons, 6 Jun 91, BYU-PFE-STL 0107585, Ex. 229, *see also*, D. Simmons laboratory telephone logs, BYU-01-1390-404, Ex. 16, and Abstract Form, BYU-PFE-Personnel Files 000107, Ex. 199.

database, maintained by the National Institute of Health that has all published DNA sequences.<sup>127</sup>

61. On or about 24 June 1991, Simmons also provided Monsanto with Appendix A to the Research Agreement,<sup>128</sup> which described in further detail Dr. Simmons's plan for the selection, testing, and modifying of NSAIDS for COX-2 selectivity, including:

- His plan to use the COX-1 and COX-2 antibodies and cDNA probes that Simmons had developed to "explore the nature of nonsteroidal anti-inflammatory drug (NSAID) interaction" with COX-1 and COX-2.
- His plan to identify "isoenzyme-specific inhibition of" COX activity.
- The planned use of "[m]urine COX-1 and COX-2 to be placed in eukaryotic expression vectors for over-expression in eukaryotic cells," so as to allow him "to express high levels of COX-1 and COX-2 in cells which express only small amounts of either enzyme."
- The development of "assays" whose "main purpose" is to "produce cell lines which express large express large amounts of either COX-1, COX-2, or both COX-1 and COX-2 together."
- A plan to "measure the COX activity of cell lines over-expressing each isoenzyme, or both enzymes," in order to "use these cells as models for intracellular inhibition of COX by NSAIDs."
- A plan to "test as many NSAIDs" as could be obtained for "their ability to inhibit COX activity in cells transfected with individual COX isoenzymes."
- A plan to develop "[d]ose-response curves" in order "to determine whether specific NSAIDS preferentially inhibit either COX," and to investigate the "mode of inhibition" also.
- A plan to "analyze expression of [COX-1 and COX-2] genes by Northern Blot following NSAID or glucocorticoid treatment."
- A plan to repeat these experiments "for human COX-1 and COX-2 when these cDNAs are available."
- A plan to research the use of cyclooxygenase in detecting and treating cancer.

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<sup>127</sup> E. Harding Dep., 8 Feb 11, 33:23-34:4, Ex. 201.

<sup>128</sup> Ltr. to L.R. Swaney from D. Simmons, 24 Jun 91, BYU-31-2911-915, Ex. 105.

62. As BYU's expert Dr. Steven Prescott has stated:

Simmons' 29 October 1989 notarized letter to Woolley, 5 April 1991 proposal to Monsanto, Appendix A to the Research Agreement, and 1991 NIH grant application—all of which he provided to Monsanto—lay out in increasing levels of detail Simmons's plan to find a COX-2 selective NSAID.<sup>129</sup>

63. Dr. Prescott also testified that, other than these documents from Dr. Simmons, he had “seen no earlier documents describing a plan to find a COX-2 selective NSAID.”<sup>130</sup>

64. On 8 July 1991, BYU signed the Research Agreement with Monsanto, which had an effective date of 1 August 1991.<sup>131</sup>

65. On 16 July 1991, Dr. Simmons's laboratory faxed Monsanto additional confidential information, namely, a side-by-side comparison of the amino acid sequences of COX-1 and COX-2.<sup>132</sup> During the same time, Dr. Simmons also shared other data with Monsanto, including the results of assays of COX-1 and COX-2 in various cells and tissues.<sup>133</sup>

66. On 24 July 1991, at Dr. Simmons's request, Dr. William Bradshaw, a BYU scientist, personally visited Monsanto and gave Monsanto scientists more confidential information, including cell lines which Dr. Simmons had proved would produce COX-2, purified COX-2 protein, antibodies to mouse COX-2, and information about these antibodies based on data and research performed at BYU.<sup>134</sup> These materials allowed Monsanto to significantly shorten the necessary process of trial and error that Monsanto would otherwise have encountered.<sup>135</sup> These antibodies represented second generation antibodies that could be used by

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<sup>129</sup> S. Prescott Expert Rpt., 18 Feb 11, Ex. 33 at ¶ 181.

<sup>130</sup> *Id.* at ¶ 182.

<sup>131</sup> Research Agreement, 1 Aug 91, BYU-11-0111-127, Ex. 9.

<sup>132</sup> Fax to Monsanto from BYU, 16 Jul 91, BYU-UR 000047361-365, Ex. 90.

<sup>133</sup> D. Simmons Decl., 1 Jun 09, Ex. 12 at ¶ 23.

<sup>134</sup> *Id.* at ¶ 26.

<sup>135</sup> *Id.* at ¶ 26.

Monsanto to compare with the first set of antibodies made against chicken COX-2 that had been sent to Monsanto on 29 April 1991.<sup>136</sup>

**5. From August 1991 Through The Termination Of The Research Agreement, Dr. Simmons Provided Monsanto With Additional Confidential Materials And Information.**

67. On or about 13 September 1991, Dr. Simmons provided Monsanto with certain 3T3 cells, which he had been specifically characterizing for COX-2 and COX-1 expression.<sup>137</sup>

68. From April 1991 through the end of 1991, Dr. Simmons and his team continued to work to identify a cell line that would express only COX-2 and not COX-1, which would then allow them to finalize an enzyme assay that would identify COX-2 selective NSAIDs.<sup>138</sup>

69. Dr. Simmons has stated that his work on the two-cell assay system was only partially completed in April of 1991:

It is important to note that each of these experiments (e.g. in vitro translation of mCOX-1 and mCOX-2, TLC analysis with exogenous H arachidonic acid, and an RIA of PGE<sub>2</sub> [standard curve] were only parts of building blocks to creating a two-cell assay. Moreover, these parts of building blocks were in their formative stage.<sup>139</sup>

70. At the beginning of August 1991, BYU's Gary Evett developed an important step in making this assay.<sup>140</sup>

71. What Dr. Simmons and his team found was that "we could use [NIH 3T3] cells as a source for COX-1 by starving the cells—that is treating them with low levels of serum and simultaneously treating them with dexamethasone. This was one of the foundational cell systems

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<sup>136</sup> D. Simmons Dep., 20-21 Apr 09, Ex. 1 at 91:6-92:24; 98:12-99:6.

<sup>137</sup> D. Simmons Amended and Supp. Expert Rpt., 10 Jun 11, Ex. 57 at ¶¶ 711-712.

<sup>138</sup> D. Simmons Decl., 17 Jun 11, Ex. 5 at ¶ 18.

<sup>139</sup> D. Simmons Amended and Supp. Expert Rpt., 10 Jun 11, Ex. 57 at ¶ 363.

<sup>140</sup> *Id.* at ¶ 649.

that we later used for testing NSAIDs. This characterization went on through October and November of that year and was relayed to Monsanto.”<sup>141</sup>

72. Dr. Simmons states that through December 1991 and into January 1992, he and his team at BYU:

performed a number of experiments on RS2 cells to characterize them as a source of COX-2. We then compared them with NIH 3T3 cells. These comparisons were being done through December and January as shown at BYU-02-0116. **These comparisons yielded a two-cell assay for NSAID testing.**<sup>142</sup>

73. Dr. Simmons goes on to say that, from November 1991 through late December of 1991 or early January of 1992, his lab “was setting up a two-cell system using NIH 3T3 cells (serum starved and DEX treated for COX-1) and stimulated RS2 cells as a source of COX-2, and [] had made measurements on these cells testing aspirin and indomethacin.”<sup>143</sup>

74. Further, Dr. Simmons states that the two-cell testing system was being done by “setting up these various cell lines for the testing of NSAIDs beginning near the start of the new year of 1992. All of this information was relayed to Monsanto.”<sup>144</sup>

75. In July 1992, Dr. Simmons met with Dr. Needleman at a scientific prostaglandin conference in Montreal, Canada.<sup>145</sup> Among other things, Dr. Simmons told Dr. Needleman that Simmons believed that Diclofenac was a COX-2 selective drug.<sup>146</sup>

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<sup>141</sup> *Id.* at ¶ 655.

<sup>142</sup> *Id.* at ¶ 665.

<sup>143</sup> *Id.* at ¶ 666.

<sup>144</sup> *Id.* at ¶ 669.

<sup>145</sup> D. Simmons Dep., 20-21 Apr 09, Ex. 1 at 34:11-20.

<sup>146</sup> D. Simmons Dep., 7-8 Nov 11, Ex. 4 at 102:5-15.

**G. BYU And Dr. Simmons Took Reasonable Steps To Guard The Confidentiality Of Their Trade Secrets.**

76. In disclosing his confidential COX-2 trade secrets to Monsanto, Dr. Simmons understood that, pursuant to standard practice in the scientific community, Monsanto would maintain the confidentiality of the materials and information.<sup>147</sup> It was also the intent of Monsanto's Dr. Needleman to keep materials received from Dr. Simmons confidential; in his words, "If it hasn't been published, we're not going to disclose it."<sup>148</sup>

77. In addition, the terms of the Research Agreement specifically protected the confidentiality of the materials and information BYU was providing to Monsanto, and limited Monsanto's use of such.

78. Professors strive to achieve balance between the need for the academic institution to publish in the academic literature and the confidentiality required for collaboration with industry.<sup>149</sup> Like other academics, Dr. Simmons was expected to, and did, publish papers and make presentations at seminars regarding his research work.<sup>150</sup> During their collaborative partnership, however, Dr. Simmons communicated with Monsanto regarding the scope of his intended seminars and academic publications.<sup>151</sup> In fact, Monsanto representatives attended conferences at which Dr. Simmons made presentations, and Monsanto never expressed any concern about the contents of Dr. Simmons's presentations.<sup>152</sup> Dr. Simmons was careful not to

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<sup>147</sup> Pls. 2<sup>nd</sup> Supp. Resp. to Defs. Interr. No. 8, 10 Dec 08, Ex. 188 at p. 10.

<sup>148</sup> P. Needleman Dep., 17-18 Nov 10, Ex. 84 at 203:24-205:19; 200:5-206:5.

<sup>149</sup> Pls. 2<sup>nd</sup> Supp. Resp. to Defs. Interr. No. 8, 10 Dec 08, Ex. 188 at p. 12.

<sup>150</sup> *Id.*

<sup>151</sup> *Id.*

<sup>152</sup> *Id.*

disclose information without Monsanto's knowledge or information which in any way could jeopardize the "Project."<sup>153</sup>

79. As an active participant in the academic community, Dr. Simmons regularly responded to requests from other researchers for samples, or aliquots, of his various trade secrets.<sup>154</sup> Dr. Simmons, aware that he both needed to maintain confidentiality of his trade secrets and fulfill his academic obligation to advance science and research pursuant to accepted academic standards, responded to certain of these requests by sending aliquots under the following conditions: (1) that the clones not be used for commercial purposes, (2) that the clones not be given to others without Dr. Simmons's consent, and (3) that any publication using his clones cite Dr. Simmons as the source of the clones.<sup>155</sup>

80. Effective August 1, 1991, with Monsanto's knowledge and consent, Dr. Simmons entered into a license agreement with Oxford Biomedical Research by which Dr. Simmons and BYU licensed (1) the "cDNA clone of murine mitogen-inducible prostaglandin G/H synthase" and (2) the "cDNA clone of murine prostaglandin G/H synthase."<sup>156</sup> Dr. Simmons continued to protect his trade secrets by licensing these clones to Oxford only for the limited purpose of allowing Oxford Biomedical Research to produce probes, antibodies, and enzymatically inactive proteins for use as a standard.<sup>157</sup>

81. Oxford's probes and antibodies were not made available to the scientific community until late 1991, well after Dr. Simmons had conveyed his clones and antibodies to Monsanto. Moreover, Oxford's antibodies sold to the scientific community were not of the same

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<sup>153</sup> *Id.*

<sup>154</sup> *Id.*

<sup>155</sup> *Id.*

<sup>156</sup> *Id.* at p. 13.

<sup>157</sup> *Id.*

concentration as the various pure stocks Dr. Simmons provided to Monsanto, nor were they accompanied with the instructions Dr. Simmons communicated to Monsanto as part of the Project.<sup>158</sup>

**H. As A Direct Result Of The Confidential Information And Materials That Monsanto Received From Dr. Simmons, Monsanto Quickly Changed Its Drug Research Program And Began Looking For A COX-2 Selective NSAID.**

**1. Prior to Dr. Simmons, Monsanto was not looking for an improved NSAID, but was looking for a steroid-like solution to inflammation.**

82. Prior to learning about Dr. Simmons and his COX-2 discoveries, Pfizer was not looking for a COX-2 selective NSAID, but was focused on a program known as “the DIP screening effort.”<sup>159</sup>

83. That effort involved focusing on “steroid related research, rather than non-steroid anti-inflammatory drugs (NSAIDs).”<sup>160</sup> This was because when the DIP project was instituted at Monsanto in 1990, it was not known whether the inducible form of cyclooxygenase “was different in structure from the constitutive form of the enzyme.”<sup>161</sup>

84. Prior to learning about COX-2 from Dr. Simmons, “Monsanto scientists were working on the basis that **any NSAID was likely to have gastric side effects.**”<sup>162</sup> In 1990, according to Monsanto’s Jaime Masferrer, “we [had] no idea that there were two clones for the cyclooxygenase.”<sup>163</sup>

85. Further, “[i]t was therefore not even known whether there was a possibility of identifying an NSAID which could selectively inhibit the inducible form of the enzyme and not

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<sup>158</sup> *Id.*

<sup>159</sup> P. Isakson Witness Statement, 23 Aug 99, Ex. 99 at ¶ 11, BYU-PFE 018576-577.

<sup>160</sup> *Id.*

<sup>161</sup> *Id.*

<sup>162</sup> *Id.* (emphasis added).



the constitutive form that was thought to play a protective role in the stomach and small intestine.”<sup>164</sup>

86. According to Pfizer’s Karen Seibert, when “Dr. Simmons showed up on April 5, 1991, [Pfizer] had not yet resolved the existence of two cyclooxygen—of the two-cyclooxygenase system.”<sup>165</sup> Dr. Seibert testified that by 5 April 1991, her group had been hypothesizing a second cyclooxygenase for 29 months,<sup>166</sup> but they “had not isolated a second form of the RNA or the gene.”<sup>167</sup>

87. Based on Monsanto’s understanding at the time, Monsanto was identifying possible steroid-like candidates in its DIP program by distinguishing them from “compounds which had NSAID-like activity.”<sup>168</sup> Because Monsanto was not looking for selective NSAIDs prior to Dr. Simmons, one step in Monsanto’s screen for a steroid-like drug was, after identifying both the steroids and NSAIDs, “to **exclude** those compounds which had NSAID activity....”<sup>169</sup>

88. Although Dr. Simmons published a paper in April 1991 disclosing his discovery of chicken COX-2, that paper did not disclose his cloning of a paired set of mouse COX-1 and COX-2 genes, nor did it disclose the nucleotide sequence of his mouse COX-2 clone.<sup>170</sup> And although Dr. Herschman from UCLA published a paper in June 1991 disclosing his cloning of a

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<sup>163</sup> J. Masferrer Dep., *Merck Frosst v. Monsanto*, 12 Dec 00, 16:23-24, BYU-PFE 106771, Ex. 48.

<sup>164</sup> P. Isakson Witness Statement, 23 Aug 99, ¶ 11, Ex. 99 at BYU-PFE 018576-577.

<sup>165</sup> K. Seibert Dep., 1-3 Jun 10, Ex. 3 at 817:13-19.

<sup>166</sup> *Id.* at 430:22-321:3.

<sup>167</sup> *Id.* at 319:6-7.

<sup>168</sup> P. Isakson Witness Statement, 23 Aug 99, ¶ 14, Ex. 99 at BYU-PFE 018578.

<sup>169</sup> *Id.* at ¶ 15 (emphasis added).

<sup>170</sup> Xie, et al, *Expression of a Mitogen-Responsive Gene Encoding Prostaglandin Synthase is Regulated by mRNA Splicing*, Proc. Natl. Acad. Sci. USA Vol. 88 (1991), BYU-18-4391-395, Ex. 54.

COX-2 gene in mouse, along with a nucleotide sequence for that clone, Dr. Herschman's sequence contained an error.<sup>171</sup>

89. In any event, as Monsanto's Dr. Isakson testified in 1999, "it **was unclear from the papers**"

whether Simmons or Herschman had in fact cloned the inducible COX enzyme which was being measured by Monsanto in the DIP assay. There was no direct link between the enzymes identified by the cloning by these group and enzyme responsible for the inducible activity seen by Monsanto.<sup>172</sup>

90. According to BYU expert Dr. Dellaria, he is "not aware of any company (including DuPont Merck, the discoverer of DuP-697) that started a selective NSAID program based on the Simmons and Herschman publications."<sup>173</sup> Rather:

Questions about Simmons and Herschman's published data needed to be answered before drug companies would be willing to start expensive COX-2 inhibitor projects. Monsanto—with access to Simmons—had the tools and information to answer these questions and start its program. Other pharmaceutical companies didn't have Simmons's unpublished tools and information and didn't immediately start COX-2 inhibitor programs after seeing the two papers.<sup>174</sup>

91. And as Pfizer expert Joseph Mancini testified, "having a [COX-1 gene/cDNA and a COX-2 gene/cDNA] would be convincing evidence to you that there were in fact two

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<sup>171</sup> Kujubu, et al., *TIS10, a Phorbol Ester Tumor Promoter-inducible mRNA from Swiss 3T3 Cells, Encodes a Novel Prostaglandin Synthase/Cyclooxygenase Homologue*, JBC, Vol. 266, No. 20, (July 15, 91), HERSCH0182-188, Ex. 55; E. Harding Dep., 8 Feb 11, Ex. 201 at 153:7-155:2 ("It was my expert opinion that the Harvey Herschman Genbank file had a sequencing error in it.").

<sup>172</sup> P. Isakson Witness Statement, 23 Aug 99, ¶ 17, Ex. 99 at BYU-PFE 018579-580 (emphasis added).

<sup>173</sup> J. Dellaria Expert Rpt., 18 Feb 11, Ex. 198 at ¶ 2.

<sup>174</sup> R. Bell Expert Rpt., 18 Feb 11, Ex. 47 at ¶ 39.

genes....”<sup>175</sup> Dr. Seibert agreed, testifying that “[t]he identification of the cDNA was—was important to saying yes, there are two messages.”<sup>176</sup>

92. Dr. Seibert also testified that Dr. Simmons’s materials “validated” the hypothesis that there “were two genes involved in cyclooxygenase synthesis.”<sup>177</sup>

93. Other pharmaceutical companies also gained the knowledge disclosed in Dr. Simmons’s April 1991 paper, and Dr. Simmons gave a related presentation at the April 1991 FASEB conference noted earlier.<sup>178</sup> But despite that general knowledge, no other pharmaceutical company was looking for a COX-2 selective inhibitor in 1991.<sup>179</sup>

94. In fact, after listening to Dr. Simmons’s presentation at the April 1991 FASEB conference, at least one prominent researcher, Dr. Dave DeWitt from the University of Michigan, still believed, based on his own research work, that there was only a single COX gene.<sup>180</sup>

95. Dr. Simmons’s presentation at the 1991 FASEB conference did motivate one scientist, Dr. Randy Bell, then working for Abbot Labs, a large pharmaceutical company, to try and convince Abbot management to start a COX-2 program.<sup>181</sup> But Abbot, after learning that prominent researcher Dr. DeWitt still believed there was only a single COX gene, was not interested in moving forward with such a program despite Dr. Simmons’s publically-presented

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<sup>175</sup> J. Mancini Dep., 7 Nov 11, Ex. 32 at 349:14-20.

<sup>176</sup> K. Seibert Dep., 1-3 Jun 10, Ex. 3 at 817:2-9.

<sup>177</sup> *Id.* at 819:3-13.

<sup>178</sup> R. Bell Dep., 29 Sep 11, Ex. 138 at 437:16-22.

<sup>179</sup> J. Mancini Dep., 7 Nov 11, Ex. 32 at 56:8-57:1.

<sup>180</sup> R. Bell Dep., 29 Sep 11, Ex. 138 at 438:1-439:3.

<sup>181</sup> *Id.* at 437:16-438:10.

findings.<sup>182</sup> At the time, of course, Dr. Simmons was not a “known name” in the cyclooxygenase world.<sup>183</sup>

96. As Pfizer’s own expert, Dr. Joseph Mancini agreed, “before senior management of a company is going to devote resources to a project, **they need to have a body of information** that’s sufficiently **convincing** to them that they should shift those resources to that project...”<sup>184</sup>

2. **After receiving Dr. Simmons’s information and materials, Monsanto changed the nature of its inflammation research, and begin looking for an improved NSAID.**

97. Although Monsanto had no COX-2 program in 1990, that changed after Monsanto received Dr. Simmons’s “body” of “convincing” information and materials in 1991:

Dr. Seibert initiated the COX-2 program at Searle/Monsanto in 1991, an effort which led to the identification and successful commercialization of the first COX-2 inhibitor, Celebrex.<sup>185</sup>

98. By early 1992, Monsanto had begun shifting resources away from its DIP project, and “began actively testing compounds in search of a selective COX-2 NSAID in early 1992.”<sup>186</sup>

99. On 8-11 January 1992, many scientists involved in COX research, including Dr. Simmons and Monsanto’s Drs. Seibert and Krivi, attended a cyclooxygenase-related meeting in Keystone, Colorado (the “Keystone Conference”).<sup>187</sup> There they attended a presentation by Dr.

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<sup>182</sup> *Id.* at 438:1-439:9.

<sup>183</sup> *Id.* at 439:4-9.

<sup>184</sup> J. Mancini Dep., 7 Nov 11, Ex. 32 at 108:24-109:11.

<sup>185</sup> Queeny Award Nomination, 17 Sep 99, Ex. 88 at BYU-PFE-651625.

<sup>186</sup> S. Prescott Expert Rpt., 18 Feb 11, Ex. 33 at ¶¶ 183-191, *quoting* Cyclooxygenase Inhibitor Project Report, 15 Jun 92, BYU-PFE 144564-591, Ex. 205 (*see* fax header on page three for date).

<sup>187</sup> D. Simmons Dep., *Univ. of Rochester v. G.D. Searle*, 16 Jul 02, 152:7-20, BYU-PFE 1200033, Ex. 17 at 151:19-152:4; Dep. of K., Seibert, *Pfizer v. Teva*, 11 Jan 06, 188:20-189:22, Ex. 18 at BYU-PFE 684464.

William Galbraith of DuPont, who presented a compound, DuP-697, as a pain reliever that did not cause gastric problems.<sup>188</sup> Dr. Seibert took notes on his presentation.<sup>189</sup>

100. In a July 1990 paper, a year and a half prior to the Keystone conference, DuP-697 had been reported as a drug that was potent yet gastric sparing, but because Dr. Simmons's COX-2 discovery had not yet been reported, pharmaceutical companies in 1990 did not have the necessary information to understand that DuP-697 was a selective COX-2 inhibitor.<sup>190</sup> Monsanto's interest in DuP-697 came only after the Research Agreement with BYU and after receiving Dr. Simmons's reagents and information.<sup>191</sup>

101. On 7 February 1992, Monsanto's Dr. Masferrer began testing for COX-2 selective NSAIDs using a two-enzyme assay approach that Simmons had described to Monsanto, and that Monsanto had developed and characterized using BYU/Simmons's antibodies and information: IL-1 induced human fetal fibroblast (HFF) cells for COX-2, and sheep seminal vesicle (SSV) cells for COX-1.<sup>192</sup>

102. On 3 March 1992, Monsanto's Dr. Len Lee synthesized DuP-697.<sup>193</sup>

103. Only days later, on 6 March 1992, Monsanto, using the two-cell assay described above that had been developed and characterized using Dr. Simmons's confidential information, screened DuP-697 in HFF and SSV.<sup>194</sup> The results of the experiment showed that DuP-697

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<sup>188</sup> D. Simmons Dep., *Univ. of Rochester v. G.D. Searle*, 16 Jul 02, 152:21-153:13, Ex. 17 at BYU-PFE 120033.

<sup>189</sup> K. Seibert Personal Notebook No. 10, Jan 92, BYU-PFE 177387-494 at 472, Ex. 59.

<sup>190</sup> J. Dellaria Expert Rpt., 18 Feb 11, Ex. 198 at ¶ 1.

<sup>191</sup> *Id.* at ¶ 3.

<sup>192</sup> S. Prescott Expert Rpt., 18 Feb 11, Ex. 33 at ¶ 260.

<sup>193</sup> L. Lee Monsanto Notebook No. 5,045,901 at 910, 3 Mar 92, PFC00637948, Ex. 20.

<sup>194</sup> J. Masferrer Monsanto Notebook No. 5,043,201 at 215, 6 Mar 92, PFC01550744, Ex. 21.

inhibited COX-2 more than COX-1, validating DuP-697 as a lead compound that Monsanto could modify to develop its own patentable, COX-2 selective inhibitor.<sup>195</sup>

104. Prior to the collaboration with BYU, Monsanto could not have conducted such a test because, as Pfizer expert Dr. Mancini acknowledged, prior to the collaboration with BYU, he is not aware that Pfizer “had a testing system in place that would test for COX-2 selectivity over COX-1 selectivity.”<sup>196</sup>

105. Use of that testing system led to an 18 March 1992 Len Lee invention disclosure form, which represented “multiple compounds” that Monsanto had determined were COX-2 selective.<sup>197</sup>

106. By at least 20 February 1992, Monsanto had an “immediate plan to test the selective COX inhibitor hypothesis.”<sup>198</sup>

107. By 18 March 1992, Monsanto chemist Dr. Len Lee had modified DuP-697 and come up with numerous potentially-patentable compounds that he believed would act as “antiinflammatory agents” by inhibiting COX-2.<sup>199</sup>

108. On 24 March 1992, Monsanto’s Dr. Seibert e-mailed Dr. Needleman to advise him that, by testing DuP-697 using a two-cell system involving both “FIB” and “SSV,” Monsanto scientists had “proven that it is a dynamite compound.”<sup>200</sup>

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<sup>195</sup> *Id.*

<sup>196</sup> J. Mancini Dep., 7 Nov 11, Ex. 32 at 344:21-345-13.

<sup>197</sup> A. Stevens Dep., 26 Oct 11, 215:17-19, Ex. 121; Disclosure of Invention, 24 Jun 92, BYU-PFE-STL 0202649, Ex. 70.

<sup>198</sup> Agenda for the COX Inhibitor Meeting, 20 Feb 92, BYU-PFE429853-55, Ex. 202.

<sup>199</sup> Disclosure of Invention by L. Lee, 24 Jun 92, BYU-PFE-STL 0202649, Ex. 70.

<sup>200</sup> Email to P. Needleman from K. Seibert, 24 Mar 92, S00664784, Ex. 42 (emphasis added).

109. Pfizer expert Mancini testified that he understood the FIB vs. SSV to mean “a system where the human fetal fibroblast cells are producing COX-1 and the SSV tissue is producing COX-2.”<sup>201</sup>

110. By no later than 15 June 1992, Monsanto’s “specific aim” was the “development of anti-inflammatory agents that act through selective inhibition of the inducible/inflammatory cyclooxygenase enzyme resulting in greater efficacy and less toxicity associated with traditional NSAIDs or glucocorticoid therapy.”<sup>202</sup>

111. Moreover, Monsanto understood that it needed to work quickly and devote significant resources to the COX-2 project; in Dr. Needleman’s words:

I want us to get there fast with the best people. **This is a horse race Monsanto/Searle should not lose.** I believe there are several generations of product activities and want to see us mobilize both shops around the problem.<sup>203</sup>

112. As a 23 July 1992 e-mail from Monsanto’s Dr. Seibert explained, Monsanto had only begun actively screening for a COX-2 selective NSAID after the Research Agreement with BYU.<sup>204</sup> Seibert reported that “significant interest in identifying a selective inducible COX NSAID has emerged ... Thus we have **in the last 6 months built** both a DIP Hit and a **COX INHIB. Hit list...**”<sup>205</sup>

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<sup>201</sup> J. Mancini Dep., 7 Nov 11, Ex. 32 at 337:18-22.

<sup>202</sup> P. Needleman Dep., 17-18 Nov 10, Ex. 84 at 265:13-14l; *see also* Cyclooxygenase Inhibitor Project Report, 16 Jun 92, BYU-PFE 144564-591, Ex. 205 (*see* fax header on page three for date).

<sup>203</sup> Email to P. Isakson from P. Needleman, 26 Jun 92, Needle-P 10000013898, Ex. 230 (emphasis added).

<sup>204</sup> S. Prescott Expert Rpt., 18 Feb 11, Ex. 33 at ¶ 193.

<sup>205</sup> Email to P. Needleman from K. Seibert, 23 Jul 92, PFC00663321-322, Ex. 231.

113. Although Monsanto for a time actively pursued both steroid-like and NSAID mechanisms of action for a selective compound, the COX-2 selective NSAID project soon overtook Monsanto's DIP project.<sup>206</sup>

114. By July 1992, Monsanto's Dr. Isakson was appointed as the "head of the Cox-2 project team."<sup>207</sup> As he testified:

It was clear that the Cox project was to be a major undertaking for Monsanto and would need to be resourced accordingly.<sup>208</sup>

115. As a 24 July 1992 Monsanto email indicates, Monsanto referred to its COX-2 project as the "Manhattan project," and "COX-2 [was] the clear primary target."<sup>209</sup>

I believe that a clear policy to direct our s/ASP resources towards **the COX-2 Manhattan project**, and keep DIP as background would be the most effective use of these efforts.<sup>210</sup>

116. As BYU expert Dr. Dellaria has stated: "Accurately recognizing the significance of the [COX-2] program was only possible through the materials and expertise provided by Simmons."<sup>211</sup> Furthermore:

It is my opinion that **Monsanto moved unusually fast in shifting resources to its COX-2 project**, indicating a strong belief in Monsanto management that the COX-2 project had sound fundamentals (target, assays, lead compound) which were brought by BYU and Simmons or in the case of the target, identified through the use of information and biological reagents supplied in the collaboration.<sup>212</sup>

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<sup>206</sup> S. Prescott Expert Rpt., 18 Feb 11, Ex. 33 at ¶ 190.

<sup>207</sup> P. Isakson Witness Statement, 23 Aug 99, ¶ 32, Ex. 99 at BYU-PFE 018587.

<sup>208</sup> *Id.* at ¶ 33.

<sup>209</sup> As the Court is doubtless aware, the "Manhattan project" was the massive research and development program instituted in the 1940s to develop the atomic bomb as quickly as possible.

<sup>210</sup> Email to P. Needleman from K. Seibert, 23 Jul 92, PFC00663321-322, Ex. 231.

<sup>211</sup> J. Dellaria Expert Rpt., 18 Feb 11, Ex. 198 at ¶ 12.

<sup>212</sup> *Id.* at ¶ 13.



**I. Monsanto Changed Its Drug Research Program By Using Directly Using Dr. Simmons's Confidential Biological Materials And Information.**

**1. Monsanto's misappropriation of Dr. Simmons's confidential biological materials and information.**

117. As noted, on 29 April 1991, Dr. Simmons sent Drs. Seibert and Masferrer his mouse COX-1 and COX-2 cDNA clones and chicken COX-2 antibodies.<sup>213</sup> Dr. Simmons also gave Drs. Seibert and Masferrer handwritten instructions on how to use these materials.<sup>214</sup>

118. Dr. Seibert admitted that BYU's COX-2 antibodies were the only existing COX-2 antibodies in the world as of 29 April 1991,<sup>215</sup> and that BYU possessed the only paired COX-1 and COX-2 clones from a single species as of 29 April 1991.<sup>216</sup> She also admitted that even as late as 24 March 1992, almost a year after receiving BYU's mCOX-1 and mCOX-2 cDNA clones, she still found them "useful."<sup>217</sup> Dr. Seibert admitted that she continued to regularly use Dr. Simmons's confidential materials through at least the end of 1992. As Dr. Seibert testified:

Q. From the time you received Dr. Simmons' reagents as recorded in the April 29, 1991, letter through the end of 1992, I see from your laboratory notebooks that you conducted a number of experiments with those reagents; is that correct?

A. Yes, sir.<sup>218</sup>

119. On 10 June 1991, Dr. Seibert sent Dr. Simmons a fax which described the value of the biological tools Dr. Simmons had provided:

Dan—a quick story I want to finish and **now we have the tools**; ... We always believed we had the wrong clone to see regulation—I hope your COX II sees the change....<sup>219</sup>

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<sup>213</sup> Ltr. to K. Seibert and J. Masferrer from D. Simmons, 29 Apr 91, BYU-PFE 059332, Ex. 15.

<sup>214</sup> *Id.*

<sup>215</sup> K. Seibert Dep., 1-3 Jun 10, Ex. 3 at 360:6-14.

<sup>216</sup> *Id.* at 359:23-360:5.

<sup>217</sup> *Id.* at 523:20-524:1.

<sup>218</sup> *Id.* at 149:23-150:4.

120. Upon receiving Dr. Simmons's clones and antibodies, Drs. Seibert and Masferrer immediately began using these biological reagents in their laboratory research.<sup>220</sup> When asked to what extent Monsanto had used BYU's antibodies or cDNA clones, Pfizer expert Dr. Mancini testified that "I believe [Pfizer] used the antibody for looking at the IL 1 fetal fibroblast trying to look for a COX-2 expression in those."<sup>221</sup> He further testified that "immunoprecipitation assays were done on synoviocytes with [BYU's] mCOX-2 antibodies."<sup>222</sup> He further testified that Pfizer used "DNA probes [from] Dr. Simmons' mCOX-1 and mCOX-2" to characterize cell systems.<sup>223</sup>

121. Dr. Seibert testified that research done with Dr. Simmons's biological reagents was for Pfizer's own purposes and not to further the cooperative effort:

Q. Did you understand that the – that the experiments that you were conducting in 1991 and 1992 [using Dr. Simmons's reagents] were done for the purpose of furthering Monsanto's cooperative agreement with Brigham Young University?

A. No, I –I didn't understand that.<sup>224</sup>

122. Dr. Seibert further testified that she was not aware of "any restrictions in the contractual agreement between BYU and Monsanto on the use of information that Monsanto received from Brigham Young,"<sup>225</sup> nor did she recall that she was told by anybody that "there was any restriction in the contractual agreement between BYU and Philip Needleman on the use of information that Monsanto received from Brigham Young University."<sup>226</sup>

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<sup>219</sup> Fax from K. Seibert to D. Simmons, 10 Jun 91, Ex. 30, BYU-08-0822.

<sup>220</sup> K. Seibert Dep., 1-3 Jun 10, Ex. 3 at 149:23-150:4.

<sup>221</sup> J. Mancini Dep., 7 Nov 11, Ex. 32 at 317:6-8.

<sup>222</sup> *Id.* at 318:20-24.

<sup>223</sup> *Id.* at 319:19-23.

<sup>224</sup> K. Seibert Dep., 1-3 Jun 10, Ex. 3 at 149:17-151:1.

<sup>225</sup> *Id.* at 151:11-18.

<sup>226</sup> *Id.* at 151:19-152:3.

123. On 29 October 1991, Dr. Needleman represented to a third party collaborator that “[t]hese tools [including the clones and antibodies received from Dr. Simmons] ... provide key information on the possible selective regulation of COX-1 vs. COX-2....”<sup>227</sup> In commenting on this statement, Dr. Seibert testified that Dr. Needleman is “a very accomplished scientist. And he recognizes that tools like antibodies and probes are going to be valuable in advancing the science.”<sup>228</sup>

124. Pfizer expert Mancini testified that as of 1991, he knew of no pharmaceutical company “other than Monsanto who [was] involved in efforts to find a COX-2 selective inhibitor.”<sup>229</sup> Likewise, Pfizer expert Ron Woodard stated in his report that companies other than Merck and Pfizer did not begin COX-2 projects until the mid to late 1990’s.<sup>230</sup> As BYU expert Randy Bell has stated, as a generality,: “Companies without access to BYU/Simmons tools and information ... did not start a COX-2 program.”<sup>231</sup>

## **2. Monsanto used Dr. Simmons’s antibodies to do extensive research.**

125. Beginning on 23 May 1991, Monsanto’s Jaime Masferrer conducted scientific experiments with the BYU antibodies delivered on 29 April 1991. Dr. Masferrer performed what are known as immunoprecipitation experiments (“IPs”) using BYU’s COX-2 antibodies.<sup>232</sup> On that date, Dr. Masferrer conducted an IP on neonatal cells with BYU’s chicken COX-2 antibodies.<sup>233</sup> The purpose of conducting an IP is to determine how much COX-2 protein is

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<sup>227</sup> Ltr. to A. Raz from P. Needleman, 29 Oct 91, BYU-PFE 142964, Ex. 232.

<sup>228</sup> K. Seibert Dep., 1-3 Jun 10, Ex. 3 at 489:12-17.

<sup>229</sup> J. Mancini Dep., 7 Nov 11, Ex. 32 at 56:8-57:1.

<sup>230</sup> R. Woodard Expert Rpt., 25 Jul 11, ¶ 65, Ex. 71; R. Woodard Dep., 11 Oct 11, 129:11-13, Ex. 214.

<sup>231</sup> R. Bell Expert Report, 18 Feb 11, Ex. 47 at ¶ 70.

<sup>232</sup> S. Prescott Expert Rpt., 18 Feb 11, Ex. 33 at ¶ 196; J. Masferrer GJ Binder, BYU-UR 000018203-217, Ex. 34.

<sup>233</sup> *Id.*

found in a biological sample.<sup>234</sup> As Pfizer expert Timothy Hla has explained, an IP is a process where a researcher mixes an antibody with a cell or tissue extract.<sup>235</sup> In this case, Dr. Masferrer used the anti-COX-2 antibodies provided by BYU.<sup>236</sup> “Then to isolate the anti-COX-2 antibody/COX-2 protein complex, a protein (protein A or protein G) linked to Sepharose beads are added and this is used to physically pull out the complex. To quantify the amount of COX-2 protein, often the cell or tissue extract has been radiolabeled with a radioactive amino acid,” and the amount of radioactive COX-2 is then measured.<sup>237</sup>

126. On 25 July, Monsanto used the purified protein provided by BYU on 24 July to improve the results from its IP experiments.<sup>238</sup> According to BYU expert Steven Prescott, the IP performed on 25 July, like the one on 23 May, shows that the chicken COX-2 antibody is COX-2 selective.<sup>239</sup> When questioned about this experiment, Pfizer expert Mancini testified that he “had a difficult time demonstrating or trying to follow that there was a selective COX-2 antibody that was provided by Simmons for use by Monsanto,” in part “because the photocopies that [he] was provided weren’t very good.”<sup>240</sup>

127. In addition, in July 1991, Monsanto used the amino acid sequences provided by Dr. Simmons on 16 July to begin making its own COX-1 and COX-2 specific antibodies. First, the amino acid sequences were used to make peptides to unique regions of the COX-1 and COX-2 protein respectively.<sup>241</sup> Those peptides were then injected into rabbits, and the natural reaction

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<sup>234</sup> T. Hla Expert Rpt., 20 Jul 11, ¶ 86, Ex. 35.

<sup>235</sup> *Id.* at ¶ 88.

<sup>236</sup> S. Prescott Expert Rpt., 18 Feb 11, Ex. 33 at ¶ 196; J. Masferrer GJ Binder, BYU-UR 000018203-217, Ex. 34.

<sup>237</sup> T. Hla Expert Rpt., 20 Jul 11, Ex. 35 at ¶ 88.

<sup>238</sup> J. Masferrer GJ Binder, Ex. 34 at BYU-UR 000018209.

<sup>239</sup> *Id.*

<sup>240</sup> J. Mancini Dep., 7 Nov 11, Ex. 32 at 317:19-23.

<sup>241</sup> D. Simmons Decl., 17 Jun 11, Ex. 5 at ¶ 12.

of the rabbits to the injection of the peptides was to create antibodies.<sup>242</sup> Among the antibodies created were ones termed 537 (COX-1), 538 (COX-1), 539 (COX-2) and 540 (COX-2).<sup>243</sup>

128. Pfizer expert Joseph Mancini, when asked whether in 1991 any other drug company was motivated to develop COX-1 and COX-2 antibodies like Monsanto had done, testified that “I don’t know if there was another company working on developing mouse COX-2 and COX-1 antibodies at that time.”<sup>244</sup>

**3. Monsanto also used Dr. Simmons’s mouse COX-1 and COX-2 clones to do Northern Blots.**

129. A Northern Blot is “a common technique [researchers] used in that time frame.”<sup>245</sup>

130. Dr. Seibert testified that the purpose of a Northern Blot was “to separate RNAs to measure their size and abundance.”<sup>246</sup> Dr. Seibert testified that she performed them because she was “hoping to advance the hypothesis” that “the COX, which is induced at the level of protein, we could observe at the level of RNA directly,”<sup>247</sup> which would further “the original hypotheticals around two forms of cyclooxygenase, advancing the science.”<sup>248</sup>

131. She did not perform Northern Blots “where you probed RNA using fragments of COX-1 and COX-2 cDNA” before June of 1991, because “the probe that [she] was using at the time was the sheep seminal vesicle probe, which we now know is the COX-1 cDNA.”<sup>249</sup>

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<sup>242</sup> *Id.*

<sup>243</sup> J. Masferrer Personal IP Notebook, PFC00320759, Ex. 233.

<sup>244</sup> J. Mancini Dep., 7 Nov 11, Ex. 32 at 321:23-322:1.

<sup>245</sup> S. Hauser Dep., 27 Oct 10, Ex. 37 at 85:8-9.

<sup>246</sup> K. Seibert Dep., 1-3 Jun 10, Ex. 3 at 388:18-389:1.

<sup>247</sup> *Id.* at 389:5-12.

<sup>248</sup> *Id.* at 389:13-17.

<sup>249</sup> *Id.* at 389:18-390:1.

132. The first time she “had the ability to do the Northern Blot directly with those cDNAs” was after receiving Dr. Simmons’s cDNA for mouse COX-1 and mouse COX-2.<sup>250</sup>

**4. Monsanto also used Dr. Simmons’s mouse COX-1 and COX-2 clones to create biological “probes” to create cellular assays.**

133. On 10 September 1991, Dr. Seibert sent a facsimile to Scott Hauser. In that transmission, Dr. Seibert stated:

Very briefly, we are interested in characterizing the regulation of the cyclooxygenase enzyme – the enzyme that is responsible for production of the prostaglandins. There appear to be two forms of COX—a basal, unstimulated COX-1 and a cytokine—inducible COX-2. We now have cDNAs for both of these COX enzymes from the mouse—our goal is to design specific oligo primers [DNA probes] that will selectively recognize only COX1 vs COX2 to examine regulation of those enzymes.

Dr. Seibert goes on to request Hauser’s assistance in “designing those oligos” and “helping me set up protection assays using them.”<sup>251</sup> Finally, Dr. Seibert notes that “[w]e would like to try to express the two cDNAs [COX-1 and COX-2] and examine if they really make PGS or not.”<sup>252</sup>

134. Monsanto’s expert Mancini testified that “a probe is a small section of the cDNA.”<sup>253</sup> When Mancini worked at Merck, Merck developed probes “internally because then [they’d] know exactly what [they] had.”<sup>254</sup>

135. Thereafter, on 24 September 1991, Dr. Seibert reported to Dr. Needleman that “our strategy to develop selective cDNA probes” was “already underway at Chesterfield – I’m doing it with Scott Hauser out there.”<sup>255</sup>

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<sup>250</sup> *Id.* at 388:18-390:19.

<sup>251</sup> Fax to S. Hauser from K. Seibert, 10 Sep 91, S01431882-886, Ex. 38.

<sup>252</sup> *Id.*

<sup>253</sup> J. Mancini Dep., 7 Nov 11, Ex. 32 at 249:24-250:1.

<sup>254</sup> *Id.* at 250:19-22.

<sup>255</sup> Email from K. Seibert to P. Needleman, 24 Sep 91, BYU-PFE 651078, Ex. 39.

136. Scott Hauser, who worked with Dr. Seibert on the effort to develop these probes, testified at deposition that “Karen used” BYU’s “cDNA for COX-1 and COX-2 to ... design selective probes for COX-1 and COX-2.”<sup>256</sup> The purpose of the probes was to “target mouse RNA for regulation by solution hybridization.”<sup>257</sup>

137. What Dr. Seibert was trying to do was to “utilize sequences which would be unique to COX-1 or 2 and build probes that were selective or unique to those, that would then be able to go in and very specifically measure RNA derived from COX-1 and COX-2.”<sup>258</sup>

138. By the end of November, 1991, Dr. Seibert was successful in placing the unique sections of Dr. Simmons’s COX-1 and COX-2 cDNA’s into vectors for use as probes for nuclease protection assays.<sup>259</sup> Those vectors were then used in “RNase protection assays, which could very specifically measure RNA derived from COX-1 or COX-2.”<sup>260</sup> And all of that work was performed “using Dan Simmons’ COX-1 and COX-2 as the starting point.”<sup>261</sup> Ultimately, these probes, according to Hauser, “were then also used for looking at COX-1 and COX-2 regulation in other cells and tissues.”<sup>262</sup>

139. As Dr. Seibert testified, once Pfizer received BYU’s COX-1 and COX-2 cDNA’s, “we had the tools in place to conduct these experiments.”<sup>263</sup>

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<sup>256</sup> S. Hauser Dep., 27 Oct 10, Ex. 37 at 141:8-14.

<sup>257</sup> *Id.* at 141:21-142:10.

<sup>258</sup> K. Seibert Dep., 1-3 Jun 10, Ex. 3 at 428:2-6.

<sup>259</sup> K. Seibert Monsanto Notebook No. 4,956,601 at 604-605, PFC1549662, Ex. 40; K. Seibert Monsanto Notebook No. 4,956,501 at 577-581, PFC01549436-644, Ex. 41; S. Hauser Dep., 27 Oct 10, Ex. 37 at 142:11-145:3.

<sup>260</sup> K. Seibert Dep., 1-3 Jun 10, Ex. 3 at 428:16-23; S. Hauser Dep., 27 Oct 10, Ex. 37 at 144-17-23.

<sup>261</sup> S. Hauser Dep., 27 Oct 10, Ex. 37 at 144:24-145:3.

<sup>262</sup> *Id.* at 144:4-10.

<sup>263</sup> K. Seibert Dep., 1-3 Jun 10, Ex. 3 at 438:12-13.

5. **Using Dr. Simmons's mouse COX-1 and COX-2 clones, Monsanto created eukaryotic expression vectors that it used to advance its drug-testing program.**

140. An expression vector permits “recombinant expression of a protein” in cells.<sup>264</sup> One purpose of expressing protein in cells is to “look at its pharmacology.”<sup>265</sup> In the context of the COX-2 program at Monsanto, “pharmacology” (according to Dr. Seibert) means to “test various compounds on the COX-1 and COX-2 expression system to—to look for compounds which may inhibit one of the COX enzymes and not the other.”<sup>266</sup>

141. As noted above, one specific element of Dr. Simmons's COX-2 research plan was that “murine COX-1 and COX-2 will be placed in eukaryotic expression vectors for over-expression in eukaryotic cells,” thus allowing “large amounts” of COX-1 and COX-2 to be expressed.<sup>267</sup>

142. When Dr. Seibert was asked if her experiments to put BYU's paired mCOX-1 and mCOX-2 clones into expression vectors was to permit Monsanto to perform drug testing, she answered: “I think having them in an expression vector would allow us to do some pharmacology, yes.”<sup>268</sup>

143. At his deposition, Dr. Hauser confirmed that Dr. Seibert successfully placed (or “subcloned” the coding region of Dr. Simmons's mCOX-1 and mCOX-2 cDNA clones into expression vectors.<sup>269</sup>

144. With regard to the mouse COX-1 enzyme received from BYU, Dr. Seibert admitted that she was able to “express” that enzyme.<sup>270</sup>

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<sup>264</sup> S. Hauser Dep., 27 Oct 10, Ex. 37 at 222:6-7.

<sup>265</sup> K. Seibert Dep., 1-3 Jun 10, Ex. 3 at 170:10-18.

<sup>266</sup> *Id.* at 469:21-480:4.

<sup>267</sup> Research Agreement, Appendix A at A-1, 1 Aug 91, Ex. 9 at BYU-11-0125.

<sup>268</sup> K. Seibert Dep., 1-3 Jun 10, Ex. 3 at 436:18-437:8.



145. When Scott Hauser asked whether he was aware at Monsanto of “any of Dr. Simmons’ clones being placed in an expression vector for the purpose of expressing COX-2,” he said “yes.”<sup>271</sup>

146. Monsanto manuscripts submitted to prestigious scientific publications, including Science and Nature, describe that “[t]he coding regions of mouse COX-1 and COX-2 (gifts of Dr. Dan Simmons, Brigham Young University) were subcloned into the baculovirus expression vector pVL1393.”<sup>272</sup> And Dr. Needleman confirmed that this document showed the expression of mCOX-2 from BYU’s materials.<sup>273</sup>

147. Monsanto’s Scott Hauser testified that other employees of Monsanto used the vectors he and Dr. Seibert created to conduct experiments to express COX-1 and COX-2 in cells.<sup>274</sup> A slide presentation dated “July 92” described that “protein expression [was] in progress,” referring to the “isolation and expression of COX-1 and COX-2.”<sup>275</sup> Dr. Seibert’s files indicate that by 18 July 1992 Monsanto had used expression vectors to successfully express BYU’s mouse COX-1 and COX-2 clones.<sup>276</sup> A 6 August 1992 document also indicates that the mouse COX-1 and COX-2 clones had been successfully expressed.<sup>277</sup> Monsanto did not receive a mouse COX-2 clone from another source until 24 August 1992.<sup>278</sup>

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<sup>269</sup> S. Hauser Dep., 27 Oct 10, Ex. 37 at 172:11-25; 174:6-20.

<sup>270</sup> K. Seibert Dep., 1-3 Jun 10, Ex. 3 at 171:8-12.

<sup>271</sup> S. Hauser Dep., 27 Oct 10, Ex. 37 at 233:22-234:4.

<sup>272</sup> Ltr. to Nature Magazine from K. Seibert with Manuscript, 5 Jan 94, Ex. 173 at PFC-1215344-362.

<sup>273</sup> P. Needleman Dep., 17-18 Nov 10, Ex. 84 at 424:7-425:5.

<sup>274</sup> S. Hauser Dep., 27 Oct 10, Ex. 37 at 175:1-176:15.

<sup>275</sup> COX-2 Meeting, Jul 92, Ex. 234 at PFC01214241; J. Masferrer 30(b)(6), 26 May 11, Ex. 85 at 125:4-10.

<sup>276</sup> COX Inhibitor Project Report, 18 Jul 92, BYU-PFE 409810, Ex. 235.

<sup>277</sup> Critical Path to Recombinant COX Enzymes, 6 Aug 92, BYU-PFE 409811, Ex. 236.

<sup>278</sup> K. Seibert Notebook No. 4,956,601 at 690, 24 Aug 92, Ex. 40 at PFC01549856.

148. According to Monsanto, it was “the *in vitro* recombinant enzyme based screening assay that provided all of the basic structure activity data for Searle’s COX-2 inhibitors.”<sup>279</sup>

**6. There is no dispute that the only mouse COX-1 clone that Monsanto ever used in its drug testing came from Dr. Simmons.**

149. Monsanto admits that:

[i]n 1992, Dr. Seibert asked a Monsanto co-worker to provide a eukaryotic expression vector containing the cDNA for COX-1. ... [S]ince Professor Simmons’ clones of COX-1 was handy, the co-worker used it for his PCR work in order to amplify the COX-1 gene. The requisite vector was created and mCOX-1 was thereafter expressed in insect cells by Monsanto.<sup>280</sup>

150. Dr. Seibert testified in her deposition that Monsanto did not have a source of mCOX-1 other than that obtained from BYU at any time.

Q. Before we go to that, other than Dan Simmons’ mCOX-1 cDNA, did you in any of the work you did at Monsanto or at Washington University have any other source of mCOX-1 cDNA?

A. Not that I recall.

Q. And I’m referring to at any time.

A. And not that I recall.<sup>281</sup>

151. Dr. Seibert further testified:

Q. In 1991, do you know a publicly available source of – did you know of a publicly available source of mouse COX-1 cDNA?

A. I don’t – I don’t recall

Q. You don’t recall –

A. I –

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<sup>279</sup> *Id.*

<sup>280</sup> Ltr. to D. Thomas from D. Hoscheit, 17 May 00, BYU-STL-0138208-210, Ex. 157.

<sup>281</sup> K. Seibert Dep., 1-3 Jun 10, Ex. 3 at 417:17-24.

Q. -- any publicly available source?

A. I don't recall any – any source.<sup>282</sup>

**J. Other Than Monsanto And Merck, No Other Pharmaceutical Company Had A COX-2 Program By 1992, And No Other Company Succeeded In Bringing A COX-2 Drug To Market.**

152. In the opinion of BYU's expert Dr. Prescott, the body of information and materials that Dr. Simmons shared with Monsanto gave it a head start, a "competitive advantage," of at least a year over other pharmaceutical companies.<sup>283</sup> Prior to the middle of 1992, Monsanto was the only pharmaceutical company in the world looking with a COX-2 inhibitor program.<sup>284</sup>

153. As the Senior Director of Medicinal Chemistry for Merck testified in a witness statement, prior to June 1992, "nobody within Merck had attempted to develop a COX-2 selective inhibitor."<sup>285</sup>

154. Merck did not begin a COX-2 program until July 1992,<sup>286</sup> and according to Pfizer expert Dr. Woodard, other pharmaceutical companies only began looking for COX-2 inhibitors in the "mid to late 1990's..."<sup>287</sup>

155. The Keystone Conference in January 1992 did not motivate Merck to begin looking for COX-2 inhibitor; rather, it was only after a July 1992 prostaglandin conference in Montreal that Merck became "very excited" about the possibility of developing a COX-2

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<sup>282</sup> K. Seibert Dep., 1-3 Jun 10, Ex. 3Ex. at 418:10-22.

<sup>283</sup> Expert report of S. Prescott, 18 Feb 11, Ex. 33 at p. 3.

<sup>284</sup> R. Woodard Dep., 11 Oct 11, at 128:2-129:19.

<sup>285</sup> First Witness Statement of P. Prasit, 23 Aug 99, ¶ 6, BYU-PFE 039030-042, Ex. 237.

<sup>286</sup> J. Mancini Dep., 7 Nov 11, Ex. 32 at 31:13-22.

<sup>287</sup> R. Woodard Dep., 11 Oct 11, Ex. 214 at 128:2-129:19.

inhibitor.<sup>288</sup> It was not until August 1992 that Merck actually tested a compound for COX-2 selectivity, thus several months after Monsanto had begun testing compounds for such.<sup>289</sup>

156. As Monsanto's Dr. Needleman has said, "In drug development, time really is money," so that, as regards an "average" drug:

**for each day that development is accelerated, there is \$1 million added to the company's sales figure. For Celebrex, this could approach \$10 million per day.**<sup>290</sup>

157. According to Dr. Randy Bell, a BYU expert and a former scientist at the global pharmaceutical company, Abbot Laboratories, other pharmaceutical companies did not begin looking for a COX-2 selective inhibitor as early as Monsanto because other pharmaceutical companies did not have access to the "package" of information and materials that Dr. Simmons's provided Monsanto.<sup>291</sup> Dr. Bell testified that, before 1995, there was a lot of "noise" in the literature relating to COX, "noise" meaning "conflicting opinions, conflicting ideas, conflicting hypotheses."<sup>292</sup>

158. He further testified that a pharmaceutical manager's job was to look at the data, "to pick that apart," and to determine whether there was "a complete enough package" of information to justify putting resources into an idea.<sup>293</sup> And because the rest of the industry did not have access to Dr. Simmons's "incredibly valuable" package of materials and information,

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<sup>288</sup> First Witness Statement of P. Prasit, 23 Aug 99, Ex. 237 at ¶¶ 7-8, BYU-PFE 039030-042; *see also* J. Mancini Dep., 7 Nov 11, Ex. 32 at 84:23-87:23.

<sup>289</sup> First Witness Statement of P. Prasit, 23 Aug 99, Ex. 237 at ¶¶ 9-10, BYU-PFE 039030-042.

<sup>290</sup> P. Needleman, "From A Twinkle In The Eye To A Blockbuster Drug," BYU-PFE 831913-916 at 914, Ex. 83.

<sup>291</sup> R. Bell Dep., 29 Sep 11, Ex. 138 at 72:7-73:14.

<sup>292</sup> *Id.* at 67:4-68:5.

<sup>293</sup> *Id.* at 72:7-73:5.

The rest of the industry had to hunt through various papers, some of them conflicting, some of them – many of them incomplete, over several years to really get a good feel.<sup>294</sup>

159. Hence, Dr. Bell testified, “at Abbot, we didn’t have a really good feel that this was a valuable target – that it was a target that we could approach into the 1993-’94 range.”<sup>295</sup> And not until 1995 did Abbot actually begin looking for a COX-2 selective compound, because not until then could Dr. Bell “convince management that we had what we needed to go forward with the project at Abbott.”<sup>296</sup>

160. By that time, however, Monsanto already had numerous patents on COX-2 selective compounds—what Dr. Bell referred to as a “huge patent wall,” and there weren’t very many chemical leads to finding any selectivity” in the remaining options.<sup>297</sup> So Abbot never got a “clinical candidate” for a COX-2 compound.

161. Dr. William Galbraith was a scientist at DuPont Merck in the 1990s, and the one who gave the January 1992 presentation about DuP-697 at the Keystone conference.<sup>298</sup> Yet he testified that his company could not prove DuP-697 was COX-2 selective because it did not have access to COX-2 cDNA clones or reagents that would allow scientists to verify cell lines producing uniquely COX-1 or COX-2.<sup>299</sup>

162. Because DuPont Merck did not have access to COX-2, after the Keystone meeting, it was not in a position to establish DuP-697’s “mechanism of action” and was not able

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<sup>294</sup> *Id.* at 73:7-10.

<sup>295</sup> *Id.* at 73:11-14.

<sup>296</sup> *Id.* at 288:12-298:1.

<sup>297</sup> *Id.* at 289:2-291:4.

<sup>298</sup> Aff’t of William Galbraith, 4 Jun 98, BYU-UR 000029015-035.

<sup>299</sup> W. Galbraith Dep., 23 Sep 11, Ex. 185 at 107:23-115:10; 117:1-117:14; 134:22-135:15; 161:20-23; 176:6-12; First Witness Statement of W. Galbraith, 23 Aug 99, BYU-PFE 022011-052, Ex. 60.

to establish a “proof of principle.”<sup>300</sup> Hence after the Keystone Conference, DuPont Merck “greatly reduced” the resources that it put on DuP-697.<sup>301</sup>

163. Dr. Galbraith also confirmed that if he had access to COX-1 and COX-2 antibodies, he would have used them to know what tissues produce COX-1 or COX-2.<sup>302</sup>

164. Dr. Galbraith agrees with Dr. Mancini that the more information a pharmaceutical company has on a potential project, “the more likely the company is going to spend money on it” because “[t]he company is in business to make a drug that’s going to help people and make money for the company.”<sup>303</sup>

165. Other than Monsanto (and Merck for the short time it was able to sell Vioxx) no other pharmaceutical company was able to successfully bring a COX-2 selective drug to market.<sup>304</sup>

166. Through the end of 2010, Pfizer had sold more than \$30 billion of Celebrex and its other COX-2 inhibitor NSAIDs.<sup>305</sup>

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<sup>300</sup> W. Galbraith Dep., 23 Sep 11, Ex. 185 at 265:2-268:17.

<sup>301</sup> *Id.* at 262:10-18.

<sup>302</sup> *Id.* at 270:19-271:22.

<sup>303</sup> *Id.* at 190:13-191:9.

<sup>304</sup> Expert Report of E. Lentz, 18 Feb 11, Ex. 25, at p. 63-64.

<sup>305</sup> Expert Report of R. Gering, 18 Feb 11, Ex. 8, at p. 78 and his Ex. 4.2. (Gering states that, through 28 February 2010, the actual sales of just Celebrex were \$29.5 billion, plus an additional \$3 billion of Bextra and Dynastat).

## LEGAL ARGUMENT

### I. SUMMARY JUDGMENT STANDARD.

“Summary judgment is a drastic remedy,” and the Tenth Circuit cautions that “any relief pursuant to Fed.R.Civ.P. 56 should be awarded with care.”<sup>306</sup> As that court stated: “Unless the moving party can demonstrate his entitlement beyond a reasonable doubt, summary judgment must be denied.” *Id.* The court should “examine the record to determine if any genuine issue of material fact” is in dispute, and in doing so should “view the evidence and draw reasonable inferences therefrom in the light most favorable to the nonmoving party.”<sup>307</sup>

“Trade-secret status is a question of fact,” and if there are “doubts as to the existence of triable issue of fact,” those doubts “must be resolved in favor of the existence of triable issues.”<sup>308</sup>

### II. BYU HAS SUFFICIENTLY IDENTIFIED A COMPILATION TRADE SECRET THAT INCLUDES A PLAN FOR DISCOVERING A COX-2-SELECTIVE DRUG THROUGH THE USE OF DR. SIMMONS’S COX-1 AND COX-2 BIOLOGICAL MATERIALS AND INFORMATION.

#### A. BYU Has Presented Facts From Which A Jury Could Find That Dr. Simmons Confidentially Shared An Identifiable, and Valuable, Compilation of Trade Secrets With Monsanto.

Under Utah’s version of the Uniform Trade Secret’s statute, a trade secret includes a “compilation” or “program”—as well as a “method, technique, or process”—that “derives independent economic value, actual or potential,” from being neither “generally known” nor “readily ascertainable by proper means.”<sup>309</sup> Pfizer argues that BYU hasn’t adequately identified its compilation trade secret, so as to “separate it from the general skill and knowledge” at the

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<sup>306</sup> *Conaway v. Smith*, 853 F.2d 789, 792 n.4 (10th Cir. 1988).

<sup>307</sup> *Byers v. City of Albuquerque*, 150 F.3d 1271, 1274 (10th Cir. 1998).

<sup>308</sup> *Harvey Barnett, Inc. v. Shindler*, 338 F.3d 1125, 1129 (10th Cir. 2003).

<sup>309</sup> U.C.A. § 13-24-2(4)(a).

time, Pfizer Mem. at 6, but Pfizer simply ignores the salient facts. From the facts related above, a jury could conclude at least the following:

- Over a period of years, Dr. Simmons's diligent scientific research resulted in the discovery of a new cyclooxygenase gene, COX-2, a discovery which Monsanto itself called the "greatest breakthrough in the treatment of arthritis and pain." SOF ¶¶ 16, 12-21.
- In 1989, Dr. Simmons was the first to recognize that his discovery might make it possible to "rationally design drugs that selectively inhibit one [COX] or the other and thus reduce unwanted side effects." SOF ¶ 22.
- Between 1989 and 1991, Dr. Simmons did further research to develop his plan and created biological tools, including mouse clones of COX-1 and 2, to help select, test, and modify COX-2 selective drugs. SOF ¶¶ 32-36.
- While looking for an industrial collaborator, Dr. Simmons took reasonable precautions to ensure that his COX-related research was kept confidential. SOF ¶¶ 37-43.
- Beginning in April 1991, Dr. Simmons began sharing with Monsanto, on a confidential basis, both his plan to select, test and modify NSAIDs, and the related biological tools and information with which to accomplish this. At that time, Monsanto was the only company in the world that had access to that body of information and materials. SOF ¶¶ 44-47.
- Prior to Dr. Simmons's meeting with Monsanto, and despite some hypotheses on the matter, neither Monsanto nor any other company in the world knew there were two cyclooxygenases, and the prevailing scientific wisdom was that there was only a single cyclooxygenase. SOF ¶¶ 26-31.
- Prior to Dr. Simmons's meeting with Monsanto, Monsanto was not looking for another NSAID. Indeed, prior to April 1991, no pharmaceutical company in the world had a plan to find, or was involved in efforts toward finding, a COX-2 selective drug. SOF ¶¶ 82-96.
- Between April 1991 and early 1992, Dr. Simmons continued to share more biological materials and information with Monsanto. By March 1992, using Dr. Simmons's tools and information, Monsanto had found a COX-2 selective compound that was potentially patentable. SOF ¶¶ 44-74.
- By mid-1992, Monsanto had formally changed its inflammation research program and launched its own intensive COX-2 project, looking for a commercially-viable COX-2 selective drug. SOF ¶¶ 97-116.



- Because of its access to Dr. Simmons's information and biological reagents, Monsanto gained an insuperable lead over every other pharmaceutical company in the development of a COX-2 selective NSAID, and Pfizer, as Monsanto's successor, is now essentially the only company marketing such a drug world-wide. SOF ¶¶ 152-165.
- The Defendants have sold over \$30 billion worth of Celebrex and other COX-2 inhibitors. SOF ¶ 166.

Utah's Supreme Court has held that, under the UTSA, whether a compilation of information constitutes a trade secret is "an intensely factual inquiry" and is therefore a jury question.<sup>310</sup> Other courts agree.<sup>311</sup> The above facts show, or at least would justify, a jury concluding that all or some of BYU's COX-2 information and materials constituted a "compilation" or "program" that derived independent economic value from being neither generally known nor readily ascertainable by proper means.

**B. BYU Has Properly and Sufficiently Identified Its Compilation Trade Secret.**

BYU has also properly and sufficiently identified its compilation trade secret. As set forth in the Statement of Facts above, BYU's amended response to Pfizer's interrogatory spelled out in considerable detail BYU's individual and compilation trade secrets, and Pfizer has not previously complained about the adequacy of that description. BYU's trade secret expert, Mr. Fellmeth, has also provided a detailed explanation, as has BYU's 30(b)(6) trade secret deponent, Mr. Ricker. Furthermore—especially given the 70 individual trade secrets that are not contested in this motion—there are adequate facts from which a jury could decide that BYU has a protectable compilation trade secret in at least some combination of materials and information.

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<sup>310</sup> *USA Power, LLC v. PacifiCorp*, 235 P.3d 749, 760, ¶ 45 (Utah 2010).

<sup>311</sup> *Rivendell Forest Products, Ltd. v. Georgia-Pacific Corp.*, 28 F.3d 1042, 1045 (10th Cir. 1994) ("the authorities hold that what constitutes a trade secret and whether one exists, as claimed, is an issue of fact," "doubts as to existence of triable issues of fact ... must be resolved in favor of the existence of triable issues" ... ).

Certainly, Dr. Simmons testified that the compilation trade secret included “the sum of the technology, information, biological materials, assistance” that he gave Monsanto, but that does not mean that BYU could—or would even try to—prove up every single interaction it had with Monsanto. Nor is it necessary for BYU to do so. The question is simply this: has BYU adduced adequate facts from which a jury could find that Pfizer misappropriated from BYU a “compilation” or “program”—or a “method, technique, or process”—that “derive[d] independent economic value, actual or potential,” from being neither “generally known” nor “readily ascertainable by proper means.”<sup>312</sup> If so, then summary judgment is not warranted. Paraphrasing the federal district court in *Uniram Technology v. Taiwan Semiconductor Mfr. Co.*, “[i]t is not true” that BYU’s claim “will survive *only if* it disclosed to [Pfizer] the exact combinations that make up its trade secrets.”<sup>313</sup>

In other words, if the evidence warrants, the jury is free to find a compilation trade secret that differs from the contours of that advocated by the plaintiff. For example, on the facts here, the jury could find that Dr. Simmons’s mouse COX-1 and COX-2 clones, as the only pair of COX clones within a single species that existed in the entire world, was itself a compilation trade secret.

In any event, here, the core of BYU’s disclosed compilation trade secret is straightforward: Dr. Simmons discovered definitive evidence that there were two COX genes, he developed a plan to “rationally design drugs that selectively inhibit one or the other and thus reduce unwanted side effects,” and he developed a body of biological tools and information to carry out that plan, a body that no one else in the world had at that time. Those tools included biological reagents, such as COX-1 and COX-2 cDNAs and antibodies, as well as a system for

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<sup>312</sup> U.C.A. § 13-24-2(4)(A).

using these tools to test, or “assay,” compounds for their COX-2 selectivity. There are many facts, or at least disputed facts, showing that BYU transmitted that core of information and materials to Monsanto, and that Monsanto made use of such in developing Celebrex. That’s all that was needed.

And even if it were true, as Pfizer alleges, that BYU’s compilation trade secret claim has “morphed” over the duration of this litigation, on the facts here that claim would be immaterial. In *Basic American, Inc. v. Shatila*, for example, Basic first identified 78 trade secrets it alleged had been misappropriated, then “subsequently narrowed this list down” to 26, then later stipulated to the dismissal of some claims, thus leaving only seven alleged trade secrets “relating to the process for manufacturing” hash brown potatoes.<sup>314</sup>

After a bench trial, the trial court ruled that the “substance of Basic’s claims, as interpreted in light of the evidence produced at trial,” was really “a single claim” which “consisted of introducing certain additives to potatoes which had been processed in a certain way.”<sup>315</sup> The court called this, the “Trade Secret,” and found that it “was a unique combination of generally known elements which was not in the public domain,” and had been developed by Basic “after considerable effort and expenditure....”<sup>316</sup> The trial court further ruled that the defendant had used Basic’s Trade Secret “as a starting point for developing” the defendant’s process of making hash browns, and had thus misappropriated the Trade Secret.<sup>317</sup>

On appeal, the Idaho Supreme Court affirmed, rejecting the defendant’s argument that the evolution of the “Trade Secret” and the “district court’s formulation” of the Trade Secret made it

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<sup>313</sup> 617 f. Supp. 2d 938, 942 (N.D. Calif. 2007) (emphasis in original).

<sup>314</sup> 992 P.2d 175, 181 (Idaho 1999).

<sup>315</sup> *Id.*, 992 P.2d at 183.

<sup>316</sup> 992 P.2d at 181, 189.

<sup>317</sup> 992 P.2d at 181-82.

“overly broad and vague.”<sup>318</sup> As the reviewing court explained, Basic had initially “defined its trade secret claims in almost excessive detail”—producing a list of nearly eighty alleged trade secrets, subsequently narrowed to seven—which the district court then “consolidated into a single paragraph,” ruling that **“when all of the elements were considered together, they constituted a compilation trade secret.”**<sup>319</sup> And while “the trial court’s formulation [did] not seem vague” to Idaho’s Supreme Court, **“even if it were,** Basic’s claim was still specific enough to support a misappropriation action.”<sup>320</sup>

Two of the elements that supported Basic’s Trade Secret were “that Basic spent almost six years developing the Golden Grill product,” and that “Basic’s Golden Grill process was unique to the industry,” both of which were “evidence that the process was not generally known or readily ascertainable.”<sup>321</sup> Similar facts support BYU’s trade secret claim here, where the evidence shows that Dr. Simmons spent years discovering COX-2, developing his COX-1 and -2 clones and antibodies, and developing a system of assays for testing compounds for COX-2 selectivity. SOF ¶¶ 12-36.

Courts have also rejected the argument that a plaintiff’s compilation trade secret claim must be disclosed in a single document that “recites all of the features for a given combination

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<sup>318</sup> 992 P.2d 175, 186 (Idaho 1999); cf. *SmithKline Beecham Pharmaceuticals Co. v. Merck & Co.*, 766 A.2d 442, 447 (Del. 2000) (Finding that the trial court “did not err by allowing Merck to refine the specifics of its claimed trade secret in light of the information it obtained from SmithKline”).

<sup>319</sup> *Id.* (emphasis added).

<sup>320</sup> *Id.*, 992 P.2d at 187 (emphasis added). In concluding that the plaintiff’s trade secret claim was sufficiently particular, the court expressly distinguished *Universal Analytic, Inc. v. Macneal-Schwendler Corp.*, 707 F. Supp. 1170 (C.D. Cal. 1989), a case Pfizer relies on at p. 6 of its Memorandum.

<sup>321</sup> 992 P.2d at 735.

secret.”<sup>322</sup> In *Uniram Technology, Inc. v. Taiwan Semiconductor Mfr’g*, for example, the defendant argued

that when an alleged trade secret consists of a combination of nonsecret elements, plaintiffs have a claim only if they can prove they disclosed to defendants **the precise combination that constitutes the secret.**<sup>323</sup>

The court disagreed, emphasizing that the defendant had “provide[d] no authority for this proposition,” and finding that the cases the defendant relied on “were not relevant in determining the level of legally required disclosure.”<sup>324</sup> Rather, the court held, “[i]nsisting on a unified description in a single integrated document” was “unnecessary,” because even if a plaintiff disclosed only “elements” of trade secrets, and “not combinations,” a defendant might nevertheless be found to have knowledge of the combination “if inferring such knowledge would be reasonable under the circumstances.”<sup>325</sup> As the court also said:

In short, a defendant’s knowledge of a secret combination will depend on how easy or difficult it is to piece together. **That is a question of fact.**<sup>326</sup>

**C. None Of The Cases That Pfizer Relies On Are Pertinent To The Facts At Issue Here.**

Although Pfizer cites a litany of cases purportedly supporting its argument that BYU has failed to sufficiently identify its compilation trade secret, none of its cases are on point. Pfizer’s cases deal with plaintiffs who have so fully failed to identify their individual trade secrets, that

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<sup>322</sup> *Uniram Technology, Inc. v. Taiwan Semiconductor Mfr’g Co.*, 617 F. Supp. 2d 938, 941 (N.D. Calif.)

<sup>323</sup> *Id.*, 617 F. Supp. 2d at 942 (emphasis added).

<sup>324</sup> 617 F. Supp. 2d at 942. Interestingly, two of the cases the court specifically found to be “not relevant,” are also ones that Pfizer relies on: *IDX Sys. Corp. v. Epic Sys. Corp.*, 285 F.3d 581 (7th Cir. 2002), *Am. Airlines, Inc. v. KLM Royal Dutch Airlines, Inc.*, 114 F.3d 108 (8th Cir. 1997). *Cf.* 617 F. Supp. 2d at 942 with Pfizer Mem. at 10, 14.

<sup>325</sup> 617 F. Supp. 2d 938, 943.

<sup>326</sup> 617 F. Supp. 2d at 943.

there is no way to prove the secrets were misappropriated. But for purposes of this motion the Court must assume that BYU has properly identified its 70 individual trade secret claims, and that BYU has facts sufficient to show the misappropriation of those individual claims.

By contrast, in *Utah Med. Prods., Inc. v. Clinical Innovations Assocs., Inc.*, the plaintiffs merely identified 17,000 pages of documents that defendant had taken, and claimed that “much” of the information in those pages was trade secrets, without saying what the information was.<sup>327</sup> And in *Bradbury Co. v. Teissier-duCros*, the court denied summary judgment as to some individual trade secrets, but granted summary judgment on others that were not sufficiently identified.<sup>328</sup> Thus, the *Bradbury* court granted summary judgment on one trade secret claim that involved an “unspecified new technology” for which plaintiff provided “no details.”<sup>329</sup> In *Universal Analytics v. MacNeal-Schwendler Corp*, the plaintiffs simply alleged that, because five employees all left and went to another firm, and that firm thereafter announced improvements to its products, there must have been a misappropriation of trade secrets.<sup>330</sup> The court properly held that to be an insufficient basis for a claim.<sup>331</sup> BYU has adduced facts here, however, showing

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<sup>327</sup> 79 F. Supp. 2d 1290 at 1311, 1313 (“Simply identifying documents and claiming that they contain trade secret information is not enough.”)

<sup>328</sup> 413 F. Supp. 2d 1209 (D. Kan. 2006).

<sup>329</sup> *Id.* at 1223.

<sup>330</sup> 707 S. Supp. 1170, 1177 (C.D. Calif. 1989).

<sup>331</sup> At pp. 6-7 of its Memorandum, Pfizer cites three other cases that have nothing to do with the proper identification of a compilation trade secret. In *Composite Marine Propellers, Inc. v. Van der Woude*, 962 F.2d 1263 (7th Cir. 1992), the court merely found that, though plaintiffs’ eight alleged trade secrets were properly identified, the “secrets” were not in fact secret, or there was no evidence of misappropriation. In *AMP Inc. v. Flesichhacker*, 823 F.2d 1199 (7th Cir 1987), the court held that merely listing pieces of information “by general item and category” was insufficient. And in *Loparex, LLC v. MPI Release Technologies, LLC*, 2011 U.S. Dist. LEXIS 32371 (S.D. Ind. 2011), the court said only that conclusory trade secret descriptions such as, a “capacity and methods to coat specific products for customers” was too vague. Nor does *Bancorp Service, LLC v. Hartford Life Ins. Co.*, 2002 U.S. Dist. LEXIS 26267 (E.D. Mo. 2002) help Pfizer (the parties “described the documents that they contend contain trade secret information,” but “they have not identified the information itself”).

that Dr. Simmons transferred a variety of specific biological materials and information to Monsanto, and that Monsanto used those materials and information in developing Celebrex. SOF ¶¶ 44-74; 97-116.

Toward the bottom of page 7 of its Memorandum, Pfizer cites *Hill v. Best Med. Int'l, Inc.*—one of many unpublished cases it relies on—alleging that it stands for the principle that a party must “specifically describe what particular combination of components it has in mind, how these components are combined, and how they operate in unique combination.”<sup>332</sup> But *Hill* did not involve a party seeking summary judgment on a trade secret compilation claim. *Hill* was a discovery dispute where the defendants sought a better answer to an interrogatory, and the quoted language came from another discovery case, *Struthers Scientific & Int'l Corp. v. Gen. Foods Corp.*<sup>333</sup> These cases don't pertain here; indeed, in response to an earlier discovery motion by Pfizer, BYU did file an amended response to Pfizer's trade secret interrogatory, and—until this motion—Pfizer gave no indication that BYU's amended interrogatory response was insufficiently specific.<sup>334</sup> And in any event, BYU has described how Dr. Simmons's vision for finding COX-2 selective drugs, combined with his COX-1 and COX-2 clones and antibodies, gave Monsanto at least a one-year head start over other pharmaceutical companies. SOF ¶¶ 152-166.

Pfizer also relies on *VFD Consulting, Inc. v. 21 Serv.*, another case whose facts bear not the slightest similarity to those here.<sup>335</sup> In that case, the court simply found that there was “absolutely *no* evidence” (emphasis in original) that the “MedDiag” system was VFD's trade secret; indeed, VFD's principal, Ms. Dolan, admitted that “she had no role in developing the

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<sup>332</sup> 2010 U.S. Dist. LEXIS 62726 (W.D. Penn. 2010).

<sup>333</sup> 51 F.R.D. 149 (D. Del. 1970).

<sup>334</sup> Ex. 188.

MedDiag computerized model,” and “never saw or operated the finished product.”<sup>336</sup> And Ms. Dolan also admitted that the materials VFD gave to the defendants were publicly available, and did not show, “with any particularity,” how she “organized or combined the materials in a manner that rises to the level of a legally protectable trade secret.”<sup>337</sup> That’s nothing like here.

Pfizer also cites the Seventh Circuit case of *IDX Systems Corp. v. Epic Systems Corp.*, and an unreported case from the Texas, *Astro Technology, Inc. v. Alliant Techsystems, Inc.*, but like other cases Pfizer relies on, these are tied to specific facts that are nothing like those here.<sup>338</sup> In *IDX Systems*, the plaintiff claimed that an entire software package it had provided contained protectable trade secrets, and offered a 43-page description of the “various features making up” the software package, but did not “separate the trade secrets from the other information that goes into any software package.”<sup>339</sup> Thus, “many of the items” in the 43-page description were “things that any user or passer-by sees at a glance,” and were “readily ascertainable by proper means.”<sup>340</sup> In contrast, this case involves not conventional software, but Dr. Simmons’s discovery of a new cyclooxygenase gene and protein, and his providing Monsanto with a package of information and materials relating to such that no other company in the world had.

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<sup>335</sup> 525 F. Supp. 2d 1037 (N.D. Calif. 2006).

<sup>336</sup> *Id.* at 1049.

<sup>337</sup> *Id.* Nor does *Jostens, Inc. v. Nat’l Computer Sys, Inc.*, 318 N.W.2d 691 (Minn., 1982) advance Pfizer’s argument. In *Jostens*, the court merely held that a trial court’s post-trial findings of fact had “support in the evidence,” and affirmed judgment for defendants. Among other things, the trial court found that an alleged software trade secret (CAD/CAM) “did not require substantial research or experimentation,” and came about through the “application of [defendant’s] general skill and knowledge to the integration of commonly available components ... .” 318 N.W.2d at 699. The court also held that an alleged “combination of otherwise known data” required more than just an assertion of such; the “combination itself must be delineated ... .” *Id.*

<sup>338</sup> 285 F.3d 581 (7th Cir. 2002); 2005 U.S. Dist. LEXIS 46248 (S.D. Tex. 2005).

<sup>339</sup> 285 F.3d at 583-84.

<sup>340</sup> 285 F.3d at 584.



*Astro Technology* is even less relevant. To begin with, the court there found it “uncontroverted” that the plaintiff had “authorized Defendants to use [plaintiff’s] proprietary information....”<sup>341</sup> Moreover, the only thing the plaintiff ever transferred to the defendants was “the **concept** of using fiber optics to obtain data from inside solid rocket motors,” along with identifying “several problems which need to be resolved” to develop the concept,” and “suggestions” on “potential ways” to address the problems.<sup>342</sup> And unlike here, the plaintiff himself had never actually tried or even tested the concept, and had “not presented evidence that the alleged trade secret gave Plaintiff any advantage over its competitors.”<sup>343</sup>

**D. Applicable Cases Dealing With Compilation Trade Secrets Support BYU’s Compilation Trade Secret Here.**

The cases that Pfizer’s Memorandum tried to distinguish—as well as significant cases that Pfizer failed to cite at all—both support BYU’s compilation trade secret here.

**1. Cases That Pfizer’s Memorandum Tries To Distinguish.**

At page 11 of its Memorandum, Pfizer tries in vain to distinguish three cases where the courts sustained compilation trade secret claims. In *USA Power, LLC v. PacifiCorp*, for example, Utah’s Supreme Court reversed a trial court ruling in which the trial court held that the “concept, vision and claimed confidential information” the plaintiff gave defendant “were of public record.”<sup>344</sup> The court found that a “**unique combination of generally known elements** or steps can qualify as a trade secret,” so long as the combination came from the “independent efforts” of the plaintiff, and the “compilation of information” itself was not “generally known or readily

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<sup>341</sup> *Astro Technology*, 2005 U.S. Dist. LEXIS 46248 at 48.

<sup>342</sup> *Id.* at 45 (emphasis added).

<sup>343</sup> *Id.*, 2005 U.S. Dist. LEXIS 46248 at 45-46.

<sup>344</sup> 235 P.3d 749, 758-58, ¶ 40 (Utah 2010).

ascertainable.”<sup>345</sup> The court held that USA Power’s “vision” of the “viability of a power plant in Mona,” Utah, in combination with three binders of information regarding the potential power plant constituted sufficient information to form a “compilation” trade secret—even though most of that information could be separately found in the public domain.<sup>346</sup>

Of course the facts here are much stronger than in *USA Power*, because here Dr. Simmons not only had a “vision” of how a COX-2 selective drug might be found, but his vision came from the discovery of a previously-unknown gene, COX-2, along with the development of a package of biological materials that no one else at the time had.

At page 11 of its Memorandum, Pfizer also brushes off *Mike’s Train House, Inc. v. Lionel, LLC*,<sup>347</sup> because there Pfizer says the plaintiff provided “specific technical design drawings and manuals,” thus erroneously suggesting that Dr. Simmons provided no specific materials to Monsanto—even though it is undisputed that Dr. Simmons did so. Moreover, a key holding in *Mike’s Train House* is that, when a compilation of information and materials is provided to a defendant, some of which is secret and some non-secret, a plaintiff “should not be obligated to identify which components of the protected material is secret.”<sup>348</sup>

Pfizer also dismisses *3M v. Pribyl*, 259 F.3d 587 (7 Cir. 2001),<sup>349</sup> because there, Pfizer says at page 11 of its Memorandum, “the plaintiff had provided operating plans and procedures for the manufacture of a particular product line.” That statement, of course, is not a material distinction at all, since Dr. Simmons not only provided Monsanto with “plans and procedures,” but also with biological materials to help effectuate such. Moreover, as the *3M* court explained:

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<sup>345</sup> 235 P.2d at 759, ¶¶ 43-44.

<sup>346</sup> 235 P.3d at 752-53, ¶ 8; 760, ¶¶ 45-46.

<sup>347</sup> 472 F.3d 398 (6th Cir. 2006).

<sup>348</sup> 472 F.3d at 411.

<sup>349</sup> 259 F.3d 587 (7th Cir. 2001).

A trade secret can exist in a combination of characteristics and components, each of which, by itself is in the public domain, but the unified process, design and operation of which, in unique combination, affords a competitive advantage and is a protectable secret.<sup>350</sup>

In *3M*, the jury found a trade secret in 3M’s “operating procedures, quality manuals, training manuals, process standards, and operator notes for using plaintiff’s equipment...”<sup>351</sup> The defendants argued, among other things, that 3M could not identify “what specific information contained within the more than 500 hundred pages of materials” could be considered “secret.”<sup>352</sup> The defendants thus suggested that “if 3M cannot point to specific items within its manuals that are not known by the industry, then 3M cannot claim a trade secret in the combined product,” but the Seventh Circuit rejected the argument.<sup>353</sup> The court explained that, to be considered a trade secret, a “pattern, technique, or process need not reach the level of invention necessary to warrant patent protection;” rather, a “trade secret can exist in a combination of characteristics and components” which, “in unique combination, affords a competitive advantage...”<sup>354</sup>

Finally, in *Lyn-Flex West, Inc. v. Dieckhaus*,<sup>24</sup> S.W.3d 693 (Mo. App. 1999), the Missouri Court of Appeals reversed a trial court’s directed verdict of a compilation trade secret comprised of a “price book” that contained “a detailed compilation of technical and non-technical data” that represented “many years’ experience in the business” that “could not be easily duplicated or properly acquired by others.”<sup>355</sup> Here, BYU has introduced facts, or at least evidence of disputed facts, showing that its compilation trade secret included “technical data,”

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<sup>350</sup> 259 F.3d at 595-96.

<sup>351</sup> 259 F.3d at 593.

<sup>352</sup> 259 F.3d at 595.

<sup>353</sup> *Id.*

<sup>354</sup> *Id.*, 259 F.3d at 595-96.

along with biological materials, that represented “many years” of research, and “could not be easily duplicated or properly acquired by others.” *See, e.g.* SOF ¶¶ 12-18, 32-36, 44-47..

## 2. Pertinent cases that Pfizer’s Memorandum failed to mention.

While Pfizer’s Memorandum cites numerous trade secret cases—including at least seven unreported cases—it fails to mention the Tenth’s Circuit’s decision in *Rivendell Forest Products, LTD. V. Georgia-Pacific Corp.*<sup>356</sup> In that case, the trial court granted summary judgment against plaintiff Rivendell’s claim that its computer software system was a compilation trade secret that Georgia-Pacific (“GP”) misappropriated. The Tenth Circuit reversed, finding issues of fact under Colorado’s trade secret statute.

*Rivendell* involved a computer software system that took plaintiff Rivendell years to build, and which allegedly enabled Rivendell “to provide its customers with special service, and to manage its distribution centers as no competitor could do.”<sup>357</sup> The defendant Cornwell knew the system well, since he learned it while working for Rivendell. Eventually GP hired Cornwell to develop a software system that would help GP manage the consolidation of its 100 distribution centers.<sup>358</sup> GP’s software system was “*very soon* developed,” and “it was for all practical purposes the same as the one at Rivendell.”<sup>359</sup>

The Tenth Circuit first noted that “the authorities hold that what constitutes a trade secret and whether one exists, as claimed, is an issue of fact.”<sup>360</sup> The court then criticized the trial court requirement that the “software system be examined bit by bit,” with the further requirement that “Rivendell demonstrate protectability of its elements or some of them **rather than the**

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<sup>355</sup> 24 S.W. 3d 693-699 (Mo. App. 1999)

<sup>356</sup> 28 F.3d 1042 (10th Cir. 1994).

<sup>357</sup> 28 F.3d 1042, 1043 (10th Cir. 1994).

<sup>358</sup> *Id.*, 28 F.3d at 1044.

<sup>359</sup> *Id.* (emphasis in original).

**protectability of the software system as a whole.**<sup>361</sup> According to the trial court, without a showing that Rivendell and GP's software systems "were similar in some protectable particular, there is no such clarity in Rivendell's claim."<sup>362</sup> The Tenth Circuit disagreed, stating:

The authorities recognize that a trade secret such as the one here claimed can consist of a combination of elements which are in the public domain.<sup>363</sup>

The Tenth Circuit also explained that:

A determination as to the existence of a trade secret as a fact issue requires doubts as to existence of triable issues of fact which must be resolved in favor of the existence of triable issues.<sup>364</sup>

The court then observed that Rivendell had presented "facts in affidavits and deposition," and that such facts were not "arguments."<sup>365</sup>

Finally, the Tenth Circuit found that: 1) a "methodology implementing the combination of concepts and ideas" had been shown; 2) that Rivendell's software was "a total package for immediate use," which, due to "the integration of the many computations as to size of lumber" and other factors, permitted "the immediate quotation of a total price," 3) that Rivendell's system was the "only system in the industry which could accomplish this"; and 4) that GP "had nothing comparable before the Defendant Cornwell was hired away from Rivendell."<sup>366</sup>

These findings are reminiscent of the facts BYU presents here, in that Dr. Simmons provided Monsanto a "total package" of concepts and materials for its "immediate use," a package which not only gave Monsanto the knowledge of a second COX gene, but gave

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<sup>360</sup> *Id.*, 28 F.3d at 1045.

<sup>361</sup> *Id.*, 28 F.3d at 1045 (emphasis added).

<sup>362</sup> 28 F.3d at 1045.

<sup>363</sup> *Id.*

<sup>364</sup> *Id.*

<sup>365</sup> *Id.*

<sup>366</sup> *Id.*, 28 F.3d at 1045-46.

Monsanto access to the only pair of mouse COX-1 and COX-2 clones in the world, along with COX antibodies and other materials and information that permitted the use of a two-cell assay system, which at the time was the “only system in the industry that could accomplish this.”<sup>367</sup>

Nor does Pfizer cite *Harvey Barnett, Inc. v. Shidler*, another case in which the Tenth Circuit reversed a trial court’s summary judgment order dismissing a trade secret claim.<sup>368</sup> That case involved Harvey Barnett’s “Infant Swimming Research program,” or “ISR,” a method of teaching infants to swim (known as the “swim, float, swim” method), which involved numerous “prompts and procedures” for teaching infants how to survive in the water. The ISR program included safety protocols and a “BUDS” Record Sheet allowing parents to monitor their children’s physical responses to the ISR program.<sup>369</sup> Barnett had written various books detailing some of the techniques and methods he used in in the ISR program.<sup>370</sup>

The defendants had previously worked for ISR, then started their own program that was allegedly similar to the ISR program, utilizing the same “swim, float, swim” method, and some (but apparently not all) of the same safety protocols, including a Daily Health Data Sheet similar to the BUDS sheet.<sup>371</sup> The district court, applying Colorado’s version of UTSA, granted summary judgment for the defendants, finding that “variations of the swim, float, swim method” were publicly known, that ISR had not taken precautions to guard the secrecy of its information until “hundreds of instructors had been trained and thousands of students taught,” and that a

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<sup>367</sup> Cf. *Tan Line Studios, Inc. v. Bradley*, 1986 U.S. Dist. LEXIS 27754, \*21, 1 U.S.P.Q.2d (BNA) 2031 (E.D. Penn. 1986) (“I find, however, that Tan-Line entire methodology for conducting a tanning studio constitutes a trade secret.”); *Uncle B’s Bakery, Inc. v. O’Rourke*, 920 F. Supp. 1405 (N.D. Iowa 1996) (“the court concludes that the entirety of Uncle B’s Bakery’s manufacturing process, from ingredients through bagging, is sufficiently unique to constitute a trade secret under Iowa law”).

<sup>368</sup> 338 F.3d 1125 (10th Cir. 2003).

<sup>369</sup> *Id.*, 338 F.3d at 1127.

<sup>370</sup> *Id.*

variation on ISR's methods could be created through a perusal of commercially available books and materials.<sup>372</sup> In reversing, the Tenth Circuit concluded that the district court "**improperly looked** at components of the ISR program **in isolation, rather than as a whole** in determining that ISR does not possess a trade secret."<sup>373</sup> As the court explained:

In failing to follow our holding in *Rivendell*—that a trade secret can exist in a **combination of characteristics**, each of which, considered separately, is in the public domain, but, **taken together, may yield a competitive advantage** that results in a protectable trade secret—the district court applied an inappropriate standard.<sup>374</sup>

The Tenth Circuit also emphasized that its "requirement of **analysis in the aggregate** is more than a formality," but is rather a "substantive component of trade-secret analysis integral to a court's ultimate conclusion regarding the existence of material facts for trial."<sup>375</sup>

In its review, the Tenth Circuit found "numerous genuine issues of material fact precluding summary judgment."<sup>376</sup> Evidence showing such facts came in the form of testimony and affidavits "attesting to the uniqueness of the ISR program."<sup>377</sup> Here, too, BYU has produced evidence of the uniqueness of the package of information and materials Dr. Simmons gave Monsanto. As BYU's expert, Dr. Bell, opined, the "set of concepts and reagents given Monsanto by Simmons in 1991 "constituted a unified plan, supporting data, and unique reagents," that "gave a large advantage to Monsanto over its industrial competitors. **No other company had**

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<sup>371</sup> 338 F.3d at 1128.

<sup>372</sup> 338 F.3d at 1129.

<sup>373</sup> 338 F.3d at 1130 (emphasis added).

<sup>374</sup> *Id.* (emphasis added).

<sup>375</sup> 338 F.3d at 1130.

<sup>376</sup> *Id.*

<sup>377</sup> 338 F.3d at 1130-31.

this set in 1991, and only Merck had much of it by mid-1993.”<sup>378</sup> BYU expert Dr. Dellaria offered a similar opinion:

At that time [in April 1991] no other research group, either academic or industrial, had access to the unique combination of Dr. Simmons clones, antibodies, research data, expert advice and project.<sup>379</sup>

Indeed, even Pfizer witnesses admitted the uniqueness of Dr. Simmons’s materials and information. Pfizer expert Dr. Mancini, for example, testified that he was not aware of any pharmaceutical companies by 1991 that were involved in efforts to find a COX-2 selective drug, other than Monsanto after its association with Dr. Simmons.<sup>380</sup> And Monsanto’s Dr. Seibert admitted that, as of 29 April 1991, she did not know “anybody else in the world who had paired cDNA clones of COX-1 and COX-2, other than Dr. Simmons,” and did not know of anybody in the world who had COX-2 antibodies, other Dr. Simmons.<sup>381</sup>

Courts have in fact found protectable compilation trade secrets in a wide variety of cases. In *Merck & Co. v. Smithkline Beecham Pharmaceuticals Co.*, for example, the Delaware Court of Chancery found a combination trade secret in the process of developing a viral vaccine, even though the underlying theoretical concepts were public knowledge.<sup>382</sup> As here, that case involved some scientific complexities; the litigants submitted post-trial briefs of “over 900 pages,” almost half of which were the defendants’ proposed findings of fact and conclusions of law.<sup>383</sup> In finding that Merck’s vaccine production process was a protectable trade secret, the court noted that the “combination of steps into a process is a trade secret, even if all the

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<sup>378</sup> SOF ¶ 47.

<sup>379</sup> Expert Report of J. Dellaria, 18 Feb 11, at p. 4, ¶ 5.

<sup>380</sup> J. Mancini Dep., 7 Nov 11, at 56:8-57:1.

<sup>381</sup> K. Seibert Dep., 1-3 Jun 10, at 359:23-360:14.

<sup>382</sup> 1999 Del. Ch. LEXIS 242 (Del. Ch. 1999), *affirmed*, 766 A.2d 442 (Del. 2000).

<sup>383</sup> *Id.* at 24.



component steps are known, so long as it is a unique process which is not known in the industry,” and that trade secret protection extends to the practical problem-solving that enables commercial application of theoretical concepts.”<sup>384</sup>

The court also emphasized that “[t]he mere fact that aspects of a trade secret process can be found in publications does not mean that the process is not a trade secret,” hence:

courts have rejected the argument that one who has learned particular information from a trade secret process is not liable if it can show that the information learned is somewhere “published.”<sup>385</sup>

Although materials may be “publicly available,” that does not mean that they are “obvious,” because such materials may not be

accompanied by instructions explaining where they were useful and where they were not, or what particular elements they described were relevant and helpful and which were not, or indeed why they should be selected over some other publicly available information.<sup>386</sup>

Hence, when a defendant has “gained valuable information from access to a trade secret,” courts don’t allow that defendant “to evade misappropriation on the basis that particular information learned from its access could be found in a publication.”<sup>387</sup>

### **III. BYU TOOK ADEQUATE MEASURES TO PROTECT ITS COMPILATION TRADE SECRET.**

Pfizer advances only a single fact in support of its argument that BYU didn’t demonstrate reasonable efforts to maintain the secrecy of its compilation trade secret: that Dr. Simmons

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<sup>384</sup> *Id.* at 52-53 (internal quotations and citations omitted).

<sup>385</sup> 1999 Del. Ch. LEXIS 242, at 54-55.

<sup>386</sup> *Id.*, quoting *Monovis, Inc. v. Aquino*, 906 F. Supp. 1205 f1228 (W.D.N.Y. 1994).

<sup>387</sup> 1999 Del. Ch. LEXIS 242 at 59-60; accord *AvidAir Helicopter Supply, Inc. v. Rolls-Royce Corp.*, 2011 U.S. App. LEXIS 24620 (8th Cir.2011) (noting that it is “**no defense**” to claim that one’s product “**could have been**” developed independently, if in fact it was developed using plaintiff’s materials) (emphasis added and internal quotation marks and citation omitted).

purportedly “admitted under oath” that his compilation trade secret was “finally communicated to Monsanto in July 1992, and perhaps even later.”<sup>388</sup> Pfizer then argues that, since the Research agreement had already been terminated by July 1992, the sharing of confidential information after that date “evidences a lack of reasonable steps to maintain its secrecy.” Pfizer Mem. at 13.

The argument is wholly specious. Assuming that Dr. Simmons did communicate confidential information to Monsanto after the Research Agreement had been terminated, even if it might be argued that that *particular piece of information* was not then protected, it hardly means that the disclosure forfeited trade secret protection for all possible combinations of information and materials that might constitute a compilation trade secret. And notably, Pfizer cites no case law for such an absurd result.<sup>389</sup>

As discussed earlier, to support BYU’s compilation trade secret claim, BYU is not required to, and does not intend to, try and prove up every single interaction it had with Monsanto. There is ample evidence from which a jury could find a compilation trade secret claim based information and materials provided Monsanto between April 1991 and March of 1992. In fact, as mentioned above, a jury could find a compilation trade secret claim based just on the unique combination of materials and information that Dr. Simmons provided Monsanto in April of 1991.

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<sup>388</sup> What Dr. Simmons testified was that, at a scientific conference in Montreal in 1992, he advised Dr. Needleman that his research showed that Diclofenac was a selective COX-2 inhibitor. D. Simmons Dep. at 101:22-102:15.

<sup>389</sup> In any event, it is by no means clear that the Research Agreement was terminated in July of 1992. Although BYU had agreed to the termination by that date, Pfizer had paid BYU for the first year of the agreement, which ended 31 July 1992, and prior to that date, Pfizer never confirmed the termination of the agreement; *cf. Smithkline Beecham Pharmaceuticals v. Merck & Co.*, 766 A.2d 442, 448 (Del. 2000) (“Whether the trade secrets were generally known or readily ascertainable and whether Merck took reasonable precautions to protect their secrecy is a question of fact.”)

**IV. BYU HAS ADVANCED SIGNIFICANT EVIDENCE THAT MONSANTO MISAPPROPRIATED ITS COMPILATION TRADE SECRET.**

**A. Significant Evidence Shows Pfizer's Misappropriation Of BYU's Compilation Trade Secrets.**

Relying on a misinterpretation of an unpublished decision—later vacated—Pfizer argues that BYU can't show that Monsanto misappropriated BYU's "project" and "compilation" trade secrets, because "BYU cannot show that Pfizer **used each of the elements** of these broadly defined combinations." Pfizer Mem. at 14 (emphasis added). But the law does not require such. Rather, the misappropriation of a compilation trade secret may be shown by circumstantial evidence, including evidence that a company changed its focus or procedures after acquiring the trade secrets in question, or evidence that the misappropriated trade secrets gave the defendant a "head start" on other companies pursuing similar goals. Plenty of evidence shows that here.

Pfizer relies on an unpublished decision in *Fast Food Gourmet, Inc. v. Little Lady Food, Inc.* to argue that a party "cannot demonstrate misappropriation simply by showing that the defendant used only part of the combination comprising the secret," because, the "**absence of any of these particular components would fail to produce the kind of pizza** that is the end result of its trade secret."<sup>390</sup> Leaving aside that this decision was later vacated, Pfizer has misrepresented it.

The cited decision was in fact merely a magistrate's discovery ruling denying the plaintiff's untimely motion to compel answers to interrogatories. The plaintiff there, FFGI, claimed that the defendants, LLFI and Kraft Foods Global, had usurped its trade secret for baking a thin crust, frozen pizza in a stone hearth oven. As the magistrate judge interpreted it,

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<sup>390</sup> 2007 U.S. Dist. LEXIS 41651, at \*18 (N.D. Ill. June 8, 2007) (emphasis added), *vacated*, 2997 U.S. Dist. LEXIS 90820 (N.D. Ill. Dec. 11, 2007) (vacating prior Mem. Opin. and Order because of a conflict of interest).

FFGI's trade secret claim required the presence of "four core components" to produce the proper pizza, and (in the sentence quoted in Pfizer's Memorandum), said that, on those facts, the "absence of any of these particular components would fail to produce the kind of pizza that is the end result of its trade secret." Since FFGI was seeking untimely discovery solely on other companies' use of one element (the oven), and not the other elements, it would not be relevant.

But that logic doesn't apply to BYU, because BYU has never claimed that the *only* way a company could produce a COX-2 selective drug was by use of Dr. Simmons's confidential trade secrets, only that his trade secrets gave Monsanto a head start in 1991, when Monsanto was the only company to access to his package of information and materials.<sup>391</sup>

Nor does the case law support Pfizer's absurd argument that, to prove misappropriation of a compilation trade secret, BYU must prove that Monsanto used "all elements" of BYU's trade secrets, including "the dozens of items" referenced in expert reports and testimony. Pfizer Mem. at 15.<sup>392</sup> Indeed, the very cases that Pfizer tries to distinguish suffice to deny summary judgment here. In *3M v. Pribyl*, for example, the court did not require 3M to state "what specific information contained within the 500 pages of materials could be considered secret," because 3M's real trade secret was the "unified process, design and operation, which, in unique combination" gave 3M a competitive advantage. Thus, even though "the 500-plus pages" of

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<sup>391</sup> Pfizer also failed to tell the Court the eventual outcome of the case, as set forth in a reported decision at 542 F. Supp. 2d 849 (N.D. Ill. 2008). The defendants, FFGI and Kraft, eventually moved for summary judgment, arguing that the alleged trade secrets were not secret and that FFGI could not demonstrate misappropriation. The trial court denied summary judgment, relying in part on opinions offered by the plaintiff's expert, Hoseney, that FFGI's "whole process" was "unique," and that he "had not heard of anyone using a stone impingement oven to manufacture frozen pizzas." 542 F. Supp. 2d at 861.

<sup>392</sup> *American Airlines v. KLM Royal Dutch Airlines*, 114 F.3d 108 (8th Cir. 1997) certainly does support such a proposition. That case turned on the "sham affidavit" doctrine, which bars a party from trying to manufacture a disputed fact by submitting an affidavit contradicting prior deposition testimony.

manuals included many materials in the public domain, when they were “collected and set out as a unified process,” that “compilation” could be considered a trade secret.<sup>393</sup> And 3M presented “evidence to support a powerful inference that defendants used 3M’s operating procedures and manuals, because there were “significant similarities” between their operations, and because “defendants gained a significant head start in their operation by using the trade secret knowledge...”<sup>394</sup> Notably, the 3M court did not require proof that defendants had used “all elements” of 3M’s compilation trade secret.

In *USA Power v. PacifiCorp*, the Tenth Circuit stated:

Accordingly, we hold that a jury can infer misappropriation under the Utah Trade Secrets Act if presented with circumstantial evidence that shows **access to information similar to the trade secret at issue.**<sup>395</sup>

The court went on to find that, because USA Power showed that the defendant “had access to its alleged trade secrets in the three binders,” and that the defendants’ Currant Creek project was “substantially similar to” USA Power’s Spring Canyon project, a jury based on just those facts “could reasonably infer that PacifiCorp misappropriated USA Power’s alleged trade secret when it built Currant Creek.”<sup>396</sup> It is again notable that the court required no proof that the defendant had used every piece of information in the three binders.

Here, it is undisputed that Monsanto had access to BYU’s compilation trade secrets. And BYU has produced a great deal of evidence that the methods and reagents Monsanto used in developing Celebrex were in fact BYU’s, or at least very similar to BYU’s, and that those gave

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<sup>393</sup> 259 F.3d at 596.

<sup>394</sup> *Id.*

<sup>395</sup> 235 P.3d 749, 761, ¶ 50 (emphasis added).

<sup>396</sup> *Id.* at 6512-652.

Monsanto a significant head start over every other pharmaceutical company. SOF ¶¶ 82-166. At a minimum, such facts suffice to raise genuine issues of fact on misappropriation.

**B. Pfizer Does Not Have A License To Use BYU's Compilation Trade Secrets.**

Pfizer also argues that, under ¶ 3.2 of the Research Agreement, it has a free license to use all of BYU's compilation trade secrets because 1) they were not patented; and 2) they were “developed in the Project” because they were not “complete” until after the effective date of the Research Agreement. But this claim patently contradicts Pfizer's prior position that all of the key information BYU shared with Monsanto was developed and shared *prior to* the effective date of the Research Agreement, and hence could not have been “developed in the project” or “obtained from the project.”<sup>397</sup> The Court should reject the argument on that ground alone.

In any event—even disregarding the two-faced nature of this argument—it wrongly assumes that BYU's compilation trade secret is an “all or nothing” matter: per Pfizer, BYU must either prove that Pfizer *misappropriated every single element* of BYU's compilation trade secret (which in its broadest form, includes every individual trade secret), or the jury can't return a verdict based on a compilation trade secret. As described above, though, that is assuredly not the law. The jury could easily find a compilation trade secret in the materials and information that BYU gave Monsanto prior to the 1 August 1991 effective date of the Research Agreement.

Moreover, contrary to Pfizer, paragraph 3.2 of the Research Agreement did not give Monsanto a free license to use BYU's confidential trade secrets. Indeed, such a claim is squarely at odds with paragraph 4.1 of the Research Agreement, which, “except as provided for” in the agreement, expressly bars Monsanto from using BYU's “Confidential Information.” Under

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<sup>397</sup> See, e.g., Mem. Dec. and Order, 4 Oct 11 (filed under seal), Ex. 7, at pp. 21-22.

Pfizer's reasoning, the court could simply disregard Research Agreement ¶ 4.1, because ¶ 3.2 would give Monsanto a license to use *all* of BYU's confidential materials and information.

But Research Agreement paragraph 3.2 deals only with "unpatented **inventions**" that were "developed in the project," and plainly an "invention" is not the same as "Confidential Information." Furthermore, as argued in response to Pfizer's motion for summary judgment No. 11, if BYU had given Pfizer materials and information that were in fact patentable, Pfizer had a duty under Research Agreement ¶ 3.3 to advise BYU of such fact, so that a patent could be obtained.

### **CONCLUSION**

For all the reasons advanced above, the Court should deny Pfizer's motion for summary judgment No. 6, and hold that genuine issues of fact prevent summary judgment on BYU's compilation trade secrets claim.

RESPECTFULLY SUBMITTED this 22 day of December 2011.

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**CERTIFICATE OF SERVICE**

I hereby certify that on the 22 day of December, 2011, I electronically filed the foregoing Response In Opposition To Defendants' Motion For Partial Summary Judgment On Plaintiffs' Claim That Defendants Have Misappropriated "Project" And "Compilation" Trade Secrets with the Clerk of the United States District, District of Utah Central Division, using the CM/ECF system which sent notification of such filing to the following:

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